Draft

40 CFR parts 152 & 156

Antimicrobial Registration Requirements

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Parts 152 and 156

[OPP- ;FRL]

RIN 2070-AD14

Registration Requirements for Antimicrobial Pesticide Products; and Other Pesticide Regulatory Changes

AGENCY: Environmental Protection Agency (EPA).

ACTION: Proposed rule.

SUMMARY: EPA is proposing to establish procedures for the registration of antimicrobial products, as well as implement other provisions of the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA), as amended by the Food Quality Protection Act. This proposal is required by FIFRA.

In addition to registration procedures for antimicrobial products, EPA also proposes to establish labeling standards for antimicrobial public health products, which will ensure that these products are appropriately labeled for the level of antimicrobial activity they demonstrate; to modify its notification process for antimicrobial products to conform to the statutorily prescribed process; and to exempt certain antimicrobial products from FIFRA regulation.

EPA believes that the new procedures and provisions will streamline and improve the registration process, increase consistency and certainty for antimicrobial producers, reduce the timeframes for EPA decisions on antimicrobial registrations, increase public health protection by ensuring the continued efficacy of antimicrobial public health pesticides, and promote international harmonization efforts.

EPA is also proposing to implement a number of general provisions of FIFRA that are not specific to antimicrobial pesticides. EPA proposes to interpret the applicability of the new FIFRA definition of "pesticide" that excludes liquid chemical sterilants from FIFRA regulation and includes nitrogen stabilizers, and to describe requirements pertaining to use dilution labeling. These proposals are intended to implement new provisions of FIFRA, and to update current regulations and procedures.

Finally, EPA is proposing technical, conforming and organizational changes to portions of its regulations on pesticide registration and labeling for clarity and understanding.

DATES: Written comments, identified by the docket number OPP- , must be received on or before [insert date 60 days after publication in the **Federal Register**].

ADDRESSES: Comments may be submitted by regular mail, electronically, or in person. Please follow the detailed instructions for each method as provided in Unit I of the SUPPLEMENTARY INFORMATION section of this notice.

FOR FURTHER INFORMATION CONTACT: Jean M. Frane, Environmental Protection Agency (7506C), 401 M St., S.W., Washington, DC 20460. Office location and telephone number: Rm. 1114B, Crystal Mall #2., 1921 Jeff Davis Highway, Arlington, VA], telephone 703-305-5944, e-mail: frane.jean@epamail.epa.gov

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this notice apply to you?

You may be potentially affected by this notice if you are a producer or registrant of antimicrobial or other pesticide products. Regulated categories and entities may include, but are not limited to:

CATEGORY	EXAMPLES	NAICS CODE
Producers	Pesticide products	32532
	Antifoulant paints	32551
	Antimicrobial pesticides	32561
	Nitrogen stabilizer products	32531
	Wood preservatives	32519
Wholesalers	Pesticide products	42291
	Antimicrobial products	42269

This table is not exhaustive, but is intended as a guide to entities likely to be regulated by this action. Certain portions of the proposal apply to all pesticide products, while others apply only to specialized categories of pesticide products, such as antimicrobial pesticides, nitrogen stabilizers or liquid chemical sterilants.

B. How can I get additional information or copies of support documents?

1. Electronically. You may obtain electronic copies of this document and various support documents from the EPA Home page at the Federal Register - Environmental Documents entry for this document under ``Laws and Regulations'' (http://www.epa.gov/fedrgstr/).

2. Fax on Demand. You may request to receive a faxed copy of this document and any supporting information by using a faxphone to call (202) 401-0527 and selecting item (_____). You may also follow the automated menu.

3. In person. The official record for this notice, as well as the public version, has been established under docket control number [insert appropriate docket #], (including

comments and data submitted electronically as described below). A public version of this record, including printed, paper versions of any electronic comments, which does not include any information claimed as CBI, is available for inspection in Rm. 119, Crystal Mall #2, 1921 Jefferson Davis Highway, Arlington, VA, from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays.

C. How and to whom do I submit comments?

You may submit comments by mail, in person, or electronically:

1. By mail. Submit written comments to: Public Information and Records Integrity Branch, Information Resources and Services Division (7502C), Office of Pesticide Programs, Environmental Protection Agency, 401 M St., S.W., Washington, DC, 401 M St., SW., Washington, DC 20460. The Document Control Office telephone number is 703-305-5805.

2. In person. Deliver written comments to: Public Information and Records Integrity Branch, in Rm. 119, CM #2, 1921 Jefferson Davis Highway, Arlington, VA.

3. Electronically. Submit your comments and/or data electronically to: opp-docket@epamail.epa.gov. Please note that you should not submit any information electronically that you consider to be Confidential Business Information (CBI). Electronic comments must be submitted as an ASCII file avoiding the use of special characters and any form of encryption. Comment and data will also be accepted on disks in WordPerfect 5.1/6.1 or ASCII file format. All comments and data in electronic form must be identified by the docket control number OPP-**[insert]**. Electronic comments on this notice may also be filed online at many Federal Depository Libraries.

D. How should I handle information that I believe is confidential?

You may claim information that you submit in response to this document as confidential by marking any part or all of that information as CBI. Information so marked will not be disclosed except in accordance with procedures set forth in 40 CFR part 2. A copy of the comment that does not contain CBI must be submitted for inclusion in the public record. Information not marked confidential will be included in the public docket by EPA without prior notice.

E. We Invite Your Comments

EPA invites you to provide your views on this proposal, approaches we have not considered, the potential impacts of the various options (including possible unintended consequences), and any data or information that you would like the Agency to consider. You may find the following suggestions helpful for preparing your comments:

1. Explain your views as clearly as possible.

2. Describe any assumptions that you used.

3. Provide solid technical information and/or data to support your views.

4. If you estimate potential burden or costs, explain how you arrived at the estimate.

5. Indicate what you support, as well as what you disagree with.

6. Provide specific examples to illustrate your concerns.

7. Make sure to submit your comments by the deadline in this notice.

8. At the beginning of your comments (e.g., as part of the ``Subject'' heading), be sure to properly identify the document you are commenting on. You can do this by providing the docket control number assigned to the notice, along with the name, date and Federal Register citation.

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III. Authority

A. The Federal Insecticide, Fungicide and Rodenticide Act

This proposal is issued under the authority of FIFRA sections 3 and 25, 7 U.S.C. 136a and 136w. Under FIFRA, a pesticide product may not be distributed or sold in the United States unless it is registered with the EPA. Registration is a licensing process in which EPA evaluates each proposed product, its uses, and its labeling to determine whether it meets the standard for registration in FIFRA sec. 3(c)(5). That standard states that, for a registration to be approved, EPA must determine that the pesticide product, when used in accordance with its intended uses and with widespread and commonly recognized practice, will not cause unreasonable adverse effects on the environment. The registration standard is a risk/benefit standard, which must take into account the economic, social and environmental costs and benefits of use.

B. The Food Quality Protection Act

On August 3, 1996, the Food Quality Protection Act (FQPA) was enacted, modifying FIFRA and the Federal Food, Drug and Cosmetic Act (FFDCA). Most of its provisions were effective immediately, although some require implementing regulations. Units IV. and V. of this preamble discuss the statutory provisions of FIFRA as amended by FQPA that this proposal would implement.

C. The Antimicrobial Regulation Technical Corrections Act

On October 30, 1998, Congress enacted the the Antimicrobial Regulation Technical Corrections Act (ARTCA), which modified the Federal Food, Drug and Cosmetic act (FFDCA) to effectively transfer authority over a number of pesticide residues to FDA. Regulatory authority over these residues had originally been transferred to EPA by FQPA. Unit XI. discusses the consequences of this statute and how EPA and FDA jurisdiction over antimicrobial pesticide residues in food has been allocated by ARTCA.

IV. Antimicrobial Provisions Addressed in this Proposal

A. Overview

The FQPA amendments to FIFRA focus attention on antimicrobial pesticides specifically, and the procedural framework under which the Agency reviews and approves applications for registration and amendment of antimicrobial pesticides. This unit discusses the new statutory provisions for antimicrobial products and how this proposal satisfies each statutory requirement.

1. Under FIFRA sec. 3(h)(1), EPA must evaluate its registration process to identify
improvements and reforms that would reduce historical review times for antimicrobial

applications.

2. FIFRA sec. 3(h)(2) defines the goals for review that process improvements should be designed to achieve, expressed as review period reduction goals for various types of applications.

3. Under FIFRA sec. 3(h)(3)(A), EPA must propose regulations that address a number of application process elements, with the goal of implementing specified process management improvements and meeting section 3(h)(2) goals. EPA is today proposing these regulations. Unit VIII discusses each of following statutorily mandated elements, and briefly describes how today's proposal addresses those requirements:

a. Defining the classes of antimicrobial use patterns.
b. Defining types of application review.
c. Conforming reviews to risks and benefits.
d. Ensuring efficacy.
e. Meeting review time goals.

4. Under FIFRA sec. 3(h)(3)(B), EPA must in its final rule consider specified types of application and process improvements that would contribute to meeting the review time goals or otherwise simplify the application process, including:

a. Certification mechanisms for applications.
b. Certification of laboratories.
c. Expanded use of notification and non-notification procedures.
d. Clarification of completeness criteria for applications.
e. Revised procedures for application review.
f. Allocation of resources.

In order to consider these topics for inclusion in the final rule, EPA must offer proposals or options for notice and comment today that could be incorporated into a final rule. EPA is today proposing regulations addressing expanded use of notification procedures (see Unit XVI) and completeness criteria (See Unit VIII.F.). EPA has considered certification mechanisms for applicants, and, as discussed in Unit IV.G., may establish such a mechanism administratively. EPA has also considered the possibility of laboratory certification programs, but is not making a specific proposal at this time.

Under FIFRA sec. 3(h)(3)(B), a final regulation must be promulgated no later than 240 days after the end of the comment period for those portions of this proposal required by FIFRA sec. 3(h).

B. Defining Classes of Antimicrobial Use Patterns

FIFRA sec. 3(h)(3)(A)(ii)(I) requires that EPA "define the various classes of antimicrobial use patterns." EPA has developed a comprehensive list of antimicrobial use patterns in conjunction with its upcoming part 158 proposal on antimicrobial data

requirements. That proposal would establish a set of data requirements that apply solely to antimicrobial pesticides. EPA has developed an appendix of all current antimicrobial use patterns, divided into 12 use categories having common exposures or other similarities. The proposal meshes with the statutory mandate to identify classes of antimicrobial use patterns by defining, for each use category, the data requirements that apply. Unit VIII.D. includes a
list of the use categories. A copy of the full draft Use Appendix is in the docket for this proposal. EPA intends its proposal of part 158 data requirements to satisfy the statutory requirement to define classes of antimicrobial use patterns.

C. Defining Types of Application Reviews

FIFRA sec. 3(h)(3)(A)(ii)(II) requires that EPA "differentiate the types of review undertaken for antimicrobial pesticides." Since the primary purpose of differentiating types of review is to ensure that review time goals are met, EPA views the statutory requirement as equivalent to defining the types of applications associated with the review periods in section 3(h)(2). Proposed § 152.445 addresses the various application types, and describes the general criteria EPA uses to characterize an application. EPA intends that this section will satisfy the statutory requirement to differentiate types of reviews, and also in part will satisfy the requirement for setting out differing levels of data requirements for various classes of products under FIFRA sec. 3(h)(3)(A)(ii)(I).

D. Conforming Degree of Review to Risks and Benefits

FIFRA sec. 3(h)(3)(A)(ii)(III) requires that EPA "conform the degree and type of review to the risks and benefits presented by antimicrobial pesticides and the function of review under this Act, considering the use patterns of the product, toxicity, expected exposure and product type."

The function of review under FIFRA for any pesticide product, not just an antimicrobial pesticide, is grounded in the registration standards of FIFRA sec. 3(c)(5). As such, EPA review must:

1. Assess the risks and benefits of the pesticide and its use, relevant to the determination of unreasonable adverse effects. In the case of a public health antimicrobial pesticide, a determination that the product is efficacious when used as directed is central to a benefits assessment.

2. Determine the adequacy of the pesticide labeling in directing the pesticide user as to intended and safe use of the pesticide, thereby minimizing potential adverse effects to the user and the environment.

EPA believes that its proposed part 158 regulation defining use categories and data requirements clearly acknowledges that different use patterns have different exposure patterns and risks. The data requirements for each use category are commensurate with the potential exposures and risks associated with that use pattern,

and in some cases are tiered so that higher exposures or higher risks require a second level of data. The amount and types of data required in and of themselves dictate a review process that is more detailed, requiring a more complex assessment, for these potentially higher exposures or higher toxicity. Therefore, in issuing part 158, EPA intends that the mandate to conform the degree and type of review to risks and benefits of use will be satisfied.

E. Ensuring Efficacy

FIFRA sec. 3(c)(5) has required since 1972 that the composition of a pesticide be such as to warrant the claims made for it, i.e., that a product work as claimed. Moreover, the registrant must ensure that the pesticide product continues to meet that efficacy standard as long as the product is registered. What has changed over time is the manner in which EPA is assured of product efficacy. Until 1980, EPA reviewed efficacy data for every pesticide product prior to registration, and thus could assure that, at least at the time of registration, each product would perform as intended. In 1980, EPA determined that, for pesticides of economic or aesthetic significance, the marketplace can be relied upon to weed out inefficacious products. EPA reasoned that because users can determine for themselves whether a product works, and are motivated by economic reasons to ensure that they are using the most efficacious products, less efficacious products would not survive in a highly competitive marketplace. Accordingly, EPA no longer routinely reviews efficacy data prior to registration for most insecticides, fungicides and herbicides and non-public health antimicrobial pesticides. Registrants must maintain data demonstrating efficacy in their files, and submit it to the Agency upon request.

EPA recognized, however, that it could not reduce its efficacy oversight of public health products and still be assured of product efficacy. The failure of public health products to work as intended could have consequences far beyond those of mere economic or aesthetic significance. Consumers and public health officials must have assurance that a product will work against pests that pose public health threats. Many public health products are antimicrobial pesticides registered to control bacteria, viruses, protozoa and other microorganisms pathogenic to man (others are insecticides and rodenticides controlling pests that are vectors of disease in man). Unlike insects or weeds, microbial pests cannot be seen, and users cannot determine by observation whether the product actually performs as claimed. Therefore, EPA cannot rely upon the users or marketplace forces to ensure product efficacy. Accordingly, EPA has continued to review efficacy data for public health products prior to registration.

Subdivision G of the Pesticide Assessment Guidelines describes the efficacy tests required, and the Labeling Guidelines for Pesticide Use Directions - Antimicrobial Products (Subdivision H) contain the performance standards that EPA uses to ensure that antimicrobial products achieve an acceptable level of efficacy for the claims made. The Pesticide Assessment Guidelines are available from the National Technical Information Service, 5285 Port Royal Road, Springfield, Va 22161.

FIFRA sec. 3(h)(3)(A)(ii)(IV) requires EPA to "ensure that the registration process is sufficient to maintain antimicrobial pesticide efficacy and that antimicrobial pesticide products continue to meet product performance standards and effectiveness levels for each type of label claim made." At first glance, this language may appear merely to reinforce the existing efficacy standard of FIFRA sec. 3(c)(5) that, to be registered, a product must be efficacious. On closer reading, however, it is clear that the language carries a broader mandate making explicit the role of the registration process in ensuring continued efficacy after registration.

EPA has relied on post-registration mechanisms, including enforcement monitoring, good laboratory practice monitoring and data audits, testingby EPA and States as co-regulators, registrant reporting under FIFRA sec. 6(a)(2) and user complaints, to target inefficacious products in the marketplace. In recent years, enforcement actions have found a number of incidents of product failure which have called into question the ability or willingness of producers to ensure and maintain the efficacy of their products after registration. As a result EPA has since 1990 undertaken a systematic testing program for antimicrobial pesticides. In cooperation with FDA, EPA has tested sterilant products and has brought a number of enforcement and regulatory actions against products found to be inefficacious. EPA is now testing tuberculocides and hospital disinfectants.

After a product has been identified as failing in efficacy, EPA may use enforcement measures (such as Stop Sale, Use and Removal Orders) to correct problems. EPA may also use remedies such as cancellation of registration under FIFRA sec. 6 to remove inefficacious products from the marketplace. EPA has found that post-registration reporting, monitoring, testing and cancellation processes can be cumbersome and time-consuming. In some cases, products that EPA has found to be inefficacious have taken years for resolution through the hearing and appeals processes available to registrants.

EPA agrees wholeheartedly that measures to strengthen the Agency's oversight of antimicrobial efficacy as part of registration are desirable. Today's proposal contains two specific provisions to improve and strengthen EPA's regulatory oversight of the efficacy of public health antimicrobial pesticides:

1. EPA proposes to incorporate into its regulations, as subpart W of part 156, the efficacy performance standards for public health products that are now contained only in its Labeling Guidelines. Unit XII. further discusses efficacy performance standards for public health antimicrobial pesticides.
2. EPA proposes to limit the duration of registrations bearing public health claims to 5 years. In order to extend the registration for an additional 5 years, each registrant would have to confirm by analysis that the product composition was the same as that in Agency files previously demonstrated to be efficacious, and that the product continued to meet efficacy standards specified in subpart W for each public health claim. Unit IX. discusses the 5-year duration provision in greater detail.

EPA believes that these two regulatory provisions will fulfill the statutory requirement that EPA ensure continued product efficacy through the registration process.

F. Implementing Deadlines for Process Management

FIFRA sec. 3(h)(3)(A)(ii)(V) requires that EPA "implement effective and reliable deadlines for process management." EPA believes that the "deadlines" referred to are those contained in FIFRA sec. 3(h)(1), which requires EPA to identify and evaluate reforms to the antimicrobial registration process; FIFRA sec. 3(h)(2), which establishes goals for reduction of review periods for antimicrobial applications for registration; and FIFRA sec. 3(h)(3)(D), which establishes default review periods that apply if EPA fails to issue its final antimicrobial rule by the statutorily required deadline. As discussed more fully in Unit VIII.H., EPA is today proposing in § 152.457 to adopt the "goal" review periods rather than the "default" review periods.

G. Certification Process for Regulatory Actions

FIFRA sec. 3(h)(3)(B)(iii)(I) requires that, in issuing final regulations, EPA must "consider the establishment of a certification process for regulatory actions involving risks
that can be responsibly managed, consistent with the degree of risk, in the most cost-efficient manner."

Certification statements are currently permitted by § 152.44(b)(2) for various types of amendments to registration when directed by EPA. Typically, EPA uses certification to accomplish specific changes to registration (frequently labeling changes). EPA has included in this proposal a broader provision that would allow the Agency to implement self-certification programs as needed in the future administratively. Unit VIII.A. discusses further this provision.

With respect to data certification, EPA has considered two self-certification programs in the recent past, and has implemented one of these. PR Notice 98-1, Self-Certification of Product Chemistry Data, was issued on January 12, 1998. In that notice, EPA describes the types of product chemistry information (product characteristics) that can be supplied to the Agency together with a self-certification that the data were conducted according to EPA Guidelines. Under this program, EPA would generally review only the summarized results of testing at the time of application, but could review full study reports if EPA determines that a complete evaluation of the study is warranted. Review of the summary results of testing rather than of the complete study report would decrease the time needed for all applications for registration of new products and reregistration of existing products.

EPA also considered a similar self-certification procedures for acute toxicity data, and intends in the future to implement such a program for antimicrobial products only.

EPA originally considered an acute toxicity data self-certification program because of a backlog of applications requiring acute toxicity data review extended review periods while applications waited in queue. The certification mechanism considered would have been available only with respect to a study indicating that the product should be assigned to Toxicity Category III or IV. The certification procedure was viewed as a means of reducing the resources needed for review, and thus making more decisions with the same level of resources. At the same time, EPA recognized that the certification procedure could also reduce to some extent the Agency's confidence in hazard and precautionary statements on labeling. Since EPA issued its notice for comment, however, the Agency has achieved a significant reduction in the backlog and consequently in the review times for applications in the queue. The Agency decided therefore not to pursue this approach to certification..

Although EPA has decided not to adopt such an approach for pesticides in general, the Agency has decided to consider a pilot program that allows applicants for registration of an antimicrobial product to certify the results of an acute toxicity study when the test data would indicate the product is in Toxicity Category I (the highest toxicity category). Because such a product would be subject to the most stringent labeling requirements, applicants would have no incentive to certify that a product of lower toxicity was in Toxicity Category I. Moreover, EPA's review of such data would add little value and would use limited resources. EPA invites comment on this proposed approach to certification of acute toxicity data.

H. Certification of Laboratories

FIFRA sec. 3(h)(3)(B)(iii)(II) requires EPA to "consider the establishment of a certification process by approved laboratories as an adjunct to the review process." EPA currently has underway a broad program across the Agency evaluating the feasibility of laboratory accreditation mechanisms for a variety of program and regulatory needs. The Office of Pesticide Programs has also been actively working with outside groups, such as the Chemical Specialties Manufacturers' Association to further their efforts to develop laboratory accreditation programs for antimicrobial products. EPA has considered whether a program could be instituted at this time for antimicrobial products, and believes that these efforts need further evaluation and development before being integrated into the Agency's regulatory programs. EPA intends to continue its cooperative work, and to fold its efforts into the larger Agency process. Thus, EPA is not today proposing a specific laboratory accreditation process as part of this rule.

I. Notification Processes

FIFRA sec. 3(h)(3)(B)(iii)(III)(aa) requires that, in issuing final regulations, EPA must use "expanded use of notification and non-notification procedures." This requirement dovetails neatly with the statutorily expanded scope of notifications under FIFRA sec. 3(c)(9). EPA is today proposing to include in new § 152.446 the procedures

to expand the use of notification as a mechanism for the label modifications directed by section 3(c)(9).

J. Revised Procedures for Application Review

FIFRA sec. 3(h)(3)(B)(iii)(III)(bb) requires that, in issuing final regulations, EPA must use "revised procedures for application review." As outlined in Unit VII, EPA's current regulations for registration of pesticide products, including antimicrobial pesticides, are generally limited to describing the applicant's and Agency's responsibilities and interactions. The summary description given in that unit is similar for all pesticides. EPA intends to issue or revise its current non-regulatory guidance documents that address the application process in greater detail. To the extent that EPA develops different procedures for antimicrobial products than for other products, EPA will make those procedures available via direct notice to affected registrants, and will make them widely available by all feasible means, including electronic accessibility.

The Agency has already implemented a number of administrative reforms to improve the process, including revised procedures for review. Since FQPA was enacted, the Agency has established a separate Division solely responsible for antimicrobial products. The new Antimicrobials Division is charged with all aspects of antimicrobial regulation, and includes a full complement of scientific personnel in biology, microbiology, chemistry, toxicology, and other scientific disciplines, as well as an ombudsman to deal directly with registrant issues and concerns.

The new Division has focussed initially on meeting the review period goals established by the statute for all new applications. To assist this effort, a dedicated Expedited Review Team has been formed for the purpose of processing notifications and screening and processing applications that are "fast-track" or with review periods of 90 days or less. By identifying and handling the less complex actions, this team allows the Division to channel its scientific and management resources into review of applications that are of higher priority or that require in-depth review. The Division has added more Product Managers, so that each Product Manager has a smaller and more focussed product universe.

The Division has also targeted increased outreach, communication and information exchange as a high priority. Training materials, information sheets, operating procedures and science reviews have been developed or reevaluated for streamlining opportunities.

Additional administrative accomplishments and plans are detailed in the Agency's first progress report to Congress, *Streamlining Registration of Antimicrobial Pesticides*, July 1997. EPA will issue this report annually as required by section 3(h)(4). Each report will identify further progress in management and administrative reforms.

K. Allocation of Resources

FIFRA sec. 3(h)(3)(B)(iii)(III)(cc) requires that, in issuing final regulations, EPA must address "allocation of appropriate resources to ensure streamlined management of antimicrobial pesticide registrations." The allocation of resources is not a reform that can be accomplished by Agency regulations, and EPA is not proposing any regulations for doing so. Budget and resource allocations are guided by Executive branch and Congressional priorities and are determined year by year based on overall needs of the Agency and the pesticide program.

L. Completeness of Applications

FIFRA sec. 3(h)(3)(B)(iii)(IV) requires that, in issuing final regulations, EPA must "clarify criteria for determination of the completeness of an application." EPA is today proposing in § 152.3 a definition of a "complete application" for all registration applications. In addition, specific to antimicrobial products, and directly responsive to the requirement of FIFRA sec. 3(h)(3)(B), EPA is proposing in § 152.450 to describe in detail the contents of an application, and the criteria that will be used to judge the completeness of the application as a whole, and of its individual components. EPA's proposals are discussed further in Unit VIII.F.

V. Other Statutory Provisions Addressed in this Proposal

A. Changes to the Definition of "Pesticide"

FQPA modified FIFRA sec. 2(u) to exclude certain liquid chemical sterilant products from the definition of "pesticide," and to include certain nitrogen stabilizer products. This provision was effective on August 3, 1996. In recognition of this provision, EPA is proposing to add a new § 152.6 entitled "Substances excluded from regulation by FIFRA." EPA has issued a notice to registrants, entitled "Liquid Chemical Sterilant Products" (PR Notice 98-2; January 15, 1998), explaining how it will treat liquid chemical sterilants affected by section 2(u). Units XIV and XV discuss chemical sterilants and nitrogen stabilizers.

B. Notification Procedures

FIFRA sec. 3(c)(9)(C) now authorizes registrants of antimicrobial products to make certain defined labeling modifications by notification to the Agency instead of amendment, and establishes a procedure for notifications and Agency decisions. This provision was effective on August 3, 1996, and the new procedures are exclusive to antimicrobial products. Today’s proposal codifies these new notification procedures. The substance of the expanded notifications permitted by FIFRA sec. 3(c)(9) is issued in notices to registrants (PR Notices), and not in today's proposal. Unit XVI discusses antimicrobial notifications.

C. Use Dilution Labeling

FIFRA sec. 3(c)(9)(D) authorizes registrants to include on their labeling precautionary statements about the product as diluted for use (use dilution labeling). This provision was effective on August 3, 1996. EPA proposes to reformat its human hazard labeling requirements in § 156.10(h) and to incorporate use dilution requirements in appropriate sections. Unit XIII.A. discusses use dilution labeling.

VI. What is an Antimicrobial Pesticide?

EPA proposes in § 152.3 a definition and interpretation of antimicrobial pesticide. The proposed definition is paraphrased from that in section 2(mm) of FIFRA, and interprets the undefined elements. Because FIFRA sec. 3(h) directs EPA to develop and implement special procedures in its regulatory program for antimicrobial pesticides, it is important that there be a well-defined and commonly understood universe of products to which the statutory provisions apply. The practical consequence of being included or excluded as an "antimicrobial pesticide" are significant for both pesticide producers and the Agency. FIFRA sec. 2(mm) defines the term "antimicrobial pesticide," carefully delineating its boundaries to mesh with the practical implementation of section 3(h) requirements. This unit discusses the definition in detail.

A. General Definition

Under FIFRA sec. 2(mm)(1)(A), an antimicrobial pesticide is defined as :

> (A) [A pesticide that] is intended to:
>
> > (i) disinfect, sanitize, reduce or mitigate growth or development of microbiological organisms; or
> >
> > (ii) protect inanimate objects, industrial processes or systems, surfaces, water, or other chemical substances from contamination, fouling or deterioration caused by bacteria, viruses, fungi, protozoa, algae, or slime;

With respect to the scope of pests covered by the definition, paragraph (i) focusses on the intended pesticidal function (disinfect, sanitize, etc.) against non-specific "microbiological organisms," while paragraph (ii) focusses on non-specific "protection" provided by the pesticide against specified microorganisms (bacteria, viruses, etc). As a practical matter, EPA believes that the term "microbiological organisms" in paragraph (i) should be considered to include each of the specific types of microorganisms in paragraph (ii)--bacteria, viruses, fungi, protozoa and algae. Therefore, EPA will consider any product intended for use against the microorganisms specified in paragraph (ii) to be an antimicrobial pesticide (subject to the exclusions discussed in Unit VI.B. and C)

Having identified the universe of substances that, based upon the intended pesticidal purpose, are antimicrobial pesticides, the definition goes on in paragraphs (1)(B) and (2) to exclude certain pesticides from the definition of antimicrobial pesticide. These exclusions may be characterized as use-based, that is, a pesticide is excluded because of how or where it is used, and not because of the pests or purpose of use.

B. Food Use Exclusion

FIFRA sec. 2(mm)(1)(B) excludes from "antimicrobial pesticide" those pesticides whose intended antimicrobial use is such that residues in food requiring regulation under section 408 or 409 of the FFDCA might result.

(B) [A pesticide that] in the intended use is exempt from, or otherwise not subject to, a tolerance under section 408 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 346a and 348) or a food additive regulation under section 409 of such Act.

In creating this exclusion, Congress recognized that applications for registration of food uses that require clearance under FFDCA require extensive data and relatively complex risk assessments that take longer to review. Moreover, obtaining an FFDCA clearance is a formal regulatory procedure. As discussed in Unit VIII.H, FIFRA sec. 3(h) establishes goals for completion of Agency review of an application for registration. In EPA's view, Congress recognized the difficulty of requiring the review timeframes for registration to encompass the complexities of FFDCA clearance as well. Accordingly, EPA believes that Congress intended the statutory definition to allow exclusion of any antimicrobial pesticide that would require the extensive clearance process of the FFDCA.

The statutory language uses the phrases "exempt from" and “not subject to" a clearance under FFDCA. The phrase "exempt from" is clear and has meaning under FFDCA: an exemption from the requirement of a tolerance is a formal regulatory determination made by EPA. Exemptions from tolerance are found in 40 CFR part 180.

The phrase "not subject to" is not a formal determination under FFDCA. Any product that bears a food use is "subject to" a tolerance, that is, a tolerance or other clearance is required, whether that tolerance has been established or not. EPA believes the statutory language may be unintentionally broad in not differentiating between food uses subject to an "existing" tolerance and those subject to a "new" tolerance. Products and uses subject to an existing tolerance do not require extensive review; only products subject to a new tolerance require such review. As written, the definition excludes both types of antimicrobial pesticides, although the apparent intent is to exclude only those requiring the lengthy and complicated tolerance-setting review associated with a new clearance.

In its discretion, EPA proposes to narrow the food use exclusion to conform to what it believes is the probable intent of Congress. Accordingly, EPA proposes to *exclude* from the definition of "antimicrobial pesticide" only products bearing one or more uses for which a *new* clearance is needed, or an amendment of an existing clearance. EPA proposes to *include* in the definition of "antimicrobial pesticide" (to exclude from the exclusion) product/uses "subject to" an existing tolerance. EPA believes that this narrower policy choice, while not required, more closely reflects the intent to include in the definition of “antimicrobial pesticide” products requiring little or no review and to exclude only products needing the extensive and time-consuming evaluation associated with the establishment of a new or amended clearance.

An antimicrobial pesticide, then, is a product bearing only non-food uses, only food uses covered by an existing clearance under FFDCA, or some combination of these two.

Given the food use exclusion, it is clear that the status of an antimicrobial

product as an "antimicrobial pesticide" within the meaning of FIFRA sec. 3(h) is not necessarily a permanent designation, but may shift according to its intended use. A product could be included or excluded from the definition if the intended use changes. The status of a pesticide as an "antimicrobial pesticide" becomes pertinent and can only be determined at the time of submission of an application for Agency decision. At that time, EPA must determine whether the pesticide application is for an antimicrobial pesticide for the purpose of the statutory definition.

The prime example of this use-dependent phenomenon is an application seeking the first food use of an antimicrobial pesticide. A product that heretofore has been an "antimicrobial pesticide" because it bears only non-food uses or tolerance-covered food uses is no longer an “antimicrobial pesticide” for purposes of EPA review and decision on that first food use action. Provisions of FIFRA applying only to "antimicrobial pesticides," notably the review periods, would not be triggered for that action. Once the food use issue is resolved or a tolerance issued, such that the food use is covered by an existing tolerance, the product may revert to "antimicrobial pesticide" status for a subsequent action.

C. Other Specific Exclusions

FIFRA sec. 2(mm)(2) contains further specific exclusions to the definition. These are intended to clarify that certain types of products that might be considered "antimicrobial pesticides" because they have a pesticidal effect on the defined types of microorganisms are nonetheless not to be regulated as antimicrobial pesticides for purposes of FIFRA sec. 3(h).

It should be noted that certain types of antimicrobial products are already excluded from regulation under FIFRA, and therefore from any coverage under this proposed rule.
Products used against fungi or microorganisms in or on man or other living animals are not pesticides because such microorganisms are not “pests” under FIFRA sec. 2(t). Products intended for use agtainst microorganisms in or on man and animals are regulated solely by FDA. This is not a change from longstanding FIFRA provisions.

1. Certain wood preservatives and antifoulant paints. Any product that is a wood preservative or antifoulant paint, and that also bears any claim for a pesticidal activity other than or in addition to those specified in section 2(mm)(1) is not an antimicrobial pesticide. The pesticidal activities that generally define an "antimicrobial pesticide" include activity against any microbiological organisms, and "protection" against the destructive effects of bacteria, viruses, fungi, protozoa, algae and slime.

Both wood preservatives and antifoulant paints (which are used to protect surfaces in contact with water such as boats) may function to protect against bacteria, fungi, etc., and thus, without a specific exclusion, would be deemed to be antimicrobial pesticides. However, since most wood preservatives also protect against insect damage and most antifoulant paints also protect against barnacles, the majority of

these products are not likely to be "antimicrobial pesticides." As discussed later in Unit VIII.H., however, some wood preservative products may be eligible for the review deadlines that apply to antimicrobial pesticides.

2. Agricultural fungicides. The definition of antimicrobial pesticide in FIFRA sec. 2(mm) excludes “agricultural fungicides.” Traditionally, the term “fungus” in an agricultural context has been used to mean microorganisms that are pathogenic to plants. Fungi (and other microorganisms) that are pathogenic to man and animals have historically been treated separately because of their public health implications. However, FIFRA sec. 2(k) defines “fungus” broadly to include a variety of other microorganisms, including rust, smut, mildew, mold, yeast and bacteria, without specific reference to whether the microorganisms are pathogenic to plants or to man and animals.

EPA intends the term “agricultural fungicide” to apply to all products applied in or on growing crops or to soil (i.e., pre-harvest application), regardless of the type of pest fungus. Although this would exclude as “antimicrobial pesticides” products applied pre-harvest against microorganisms that might be pathogenic to man and animals, EPA is not aware that any pesticides are currently registered against human and animal pathogens on growing crops. EPA would regulate such products if the need arose, but they would not be covered by subpart W.

A product intended for post-harvest application against fungi (including bacteria) would not be an “agricultural fungicide.” Significantly, however, such a product would not necessarily be an “antimicrobial pesticide” either, since the food use exclusion also comes into play. Post-harvest application of fungicides or antimicrobial products to food or feed crops would run afoul of the food use exclusion if a new or amended tolerance were needed to cover pesticide residues. All post-harvest use antimicrobial products would be subject to subpart W generally; however, not all would be “ antimicrobial pesticides” eligible for the review periods in § 152.457.

Given the statutory exclusions concerning fungi in or on man and animals, and the agricultural exclusion, the fungicides that remain within the definition of "antimicrobial pesticide" are:

a. Products used against fungi that are pathogenic to man and animals but not used *in or on* man or animals.

b. Products used against fungi that are destructive of articles, surfaces, systems and processes, whether or not pathogenic to man and animals.

c. Products used against fungi that may affect crops or plants after harvest, whether or not pathogenic to man and animals.

3. Aquatic herbicides. Further, the definition of antimicrobial pesticide excludes aquatic herbicide products. EPA interprets the term aquatic herbicide to mean pesticides used in or near environmental bodies of water, such as lakes, streams, or ponds, for the control of algae or weeds. In contrast, a product intended for control of algae in industrial systems or processes or swimming pools would be considered an antimicrobial product.

D. Products Included

Finally, section 2(mm)(3) lists a number of products that are deemed to be antimicrobial pesticides, to ensure that they are not inadvertently excluded by application of the various exclusions elsewhere. These include chemical sterilants other than those excluded under FIFRA sec. 2(u), other disinfectant products, industrial microbiocides, and preservatives other than wood preservatives.

VII. Current Registration Procedures for Pesticides

Under FIFRA prior to FQPA, antimicrobial pesticides were not singled out as a class of pesticide products requiring special procedural attention. Antimicrobial pesticides were registered using the same procedures and policies as other pesticide products. Antifoulants, wood preservatives and traditional antimicrobial pesticides were in separate organizational units within EPA.

A. Overview of Procedures

A brief discussion of the registration procedures which have applied to all products follows. Even though products that are "antimicrobial pesticides" will now be subject to a more carefully drawn and rigorously applied regulatory program, the basic procedures for registration will continue to apply.

1. A person seeking to register any pesticide product must submit an application for registration. That application contains information on the pesticide, copies of the proposed labeling of the product, and data of various types supporting the registration (such as chemistry, toxicology, environmental fate, ecological effects). If a food use is involved, data supporting a clearance for residues in food are also required, and if the product is of public health significance, efficacy data must be submitted. Current regulations governing submission of applications are found in 40 CFR part 152. Data requirements are described in 40 CFR part 158, and labeling requirements in 40 CFR part 156. The tolerance-setting process is contained in 40 CFR part 180.

2. At EPA, the application is processed in several stages, each of which evaluates different elements of the application.

a. A "front end" process assigns administrative numbers, checks that basic elements are contained in the application, does a data check for formatting purposes,

and packages the application for review.

b. The application package is directed to the appropriate review Division and thence to a Product Management (PM) team. Until recently two Divisions, the Registration Division, and the Biopesticides and Pollution Prevention Division, were the regulatory Divisions which reviewed all applications. Antimicrobial pesticide applications were processed within one branch, and antifoulants and wood preservatives were located in a different branch, both in the Registration Division. EPA has established a separate Antimicrobials Division (AD) to help focus its regulatory management of these products, and antifoulants and most wood preservatives are also now assigned to this Division.

c. The PM team enters the application into a tracking system, reviews product labeling and data compensation elements, and determines whether a scientific review is needed. Every application for new registration contains some data; the amount and type of data vary depending on the type of product, its composition and uses. Even applications without new data often require scientific consultation to determine the relevance and adequacy of existing data to support the application.

d. If a scientific review is needed, the PM team sends the application and data to various scientific reviewers. These reviews are generally conducted in parallel, although certain assessments must await the results of other reviews (for example, ecological effects risk assessment may depend upon the environmental fate profile of the chemical).

3. Upon completion of all reviews, the PM team consolidates review recommendations and decisions and determines whether the product can be registered. If it can, EPA issues a registration, approves the labeling (often with required modifications), and notifies the applicant. If the application cannot be approved, the PM notifies the applicant of deficiencies (data, labeling, administrative) that must be corrected before proceeding.

Once issued, a registration may be amended by submission of an application for amendment, which undergoes a similar review process as outlined above. The significant difference is that many amendments are administrative, or require no scientific review, and thus entail a less intensive and time-consuming process. Often amendments can be handled entirely within a PM team. Some minor modifications to registration can be accomplished by notification; these are modifications EPA has determined have no potential for adverse effects. Notifications require the most minimal review, primarily to ensure compliance with pre-existing Agency policies or guidance.

B. Volume of Work

Typically, applications for new registration comprise about one-third of the applications processed by the Agency, but require more time and resources per

application because of the scientific review involved. Applications for registration of new chemicals and major new uses require the most resources, but are relatively few in number. For sheer numbers, the bulk of registration actions are (and likely will continue to be) amendments to existing registrations that require no scientific review (so-called "fast track" amendments). In FY 1997, ending September 1997, EPA received a total of 635 actions related to new applications for registration of pesticides assigned to AD, including 11 high-resource new chemicals. In addition, there were 1,189 actions related to amendments to existing registrations, including 61 high-resource new uses. The number of "actions" includes both initial submissions of applications for new and amended registration and resubmissions of information after EPA has notified the applicant that the application is deficient.

Finally, there were 506 notifications for antimicrobial products, which under FIFRA sec. 3(c)(9) must be reviewed and a decision issued within 30 days of receipt. While these require minimal review, the large volume coupled with the short review time requires dedicated resources.

C. Review Times

As with any complex process, the speed at which an application can be reviewed and a decision made depends upon many things, some within the control of the Agency, others dependent upon the applicant. FIFRA prescribes in section 3(c)(3) that an application decision be reached "as expeditiously as possible." Until modified by FQPA, FIFRA contained only a single statutory decision deadline of 90 days, for so-called "fast-track" applications--those which require no review of scientific data. This review time is predicated upon receipt of a "complete" application. EPA is not required to review and reach a decision on a fast-track application until it is deemed to be complete (however, EPA must determine whether such an application is complete within 45 days after receipt).

"Fast-track" deadlines continue to apply to all products, including antimicrobial pesticides. For antimicrobial pesticides, however, FIFRA as modified by FQPA imposes additional statutory review periods.

D. Non-Regulatory Guidance Documents

EPA uses detailed guidance documents to amplify, clarify, and interpret its regulations in areas such as data and labeling development and review, process changes, and applicant responsibilities. EPA has developed a number of documents, which are available to applicants and registrants, to elaborate on the general regulations. In particular:

1. A guidance document called simply the "Blue Book" provides specific details about the application process.

2. The Labeling Manual contains guidance for developing labeling which

complies with FIFRA and EPA regulations.

3. The Pesticide Assessment Guidelines describe test methods, standards and data reporting requirements used to satisfy data requirements.

4. Standard Evaluation Procedures describe how EPA will review and evaluate each type of study submitted in support of registration.

5. EPA uses direct notice to registrants (PR Notices) to inform them of procedural changes, to clarify and interpret its regulations in specific circumstances, and for general information purposes.

All of these will continue to apply to antimicrobial pesticides. Given the special attention FIFRA now focusses on antimicrobial products, EPA may develop specific guidance documents for antimicrobial pesticides that would augment or replace existing guidance.

VIII. Proposed Antimicrobial Procedures

This unit discusses in detail the proposed procedural regulations applicable to antimicrobial products. Proposed changes that apply to all pesticides are discussed in later units of this preamble.

A. Organization of Proposed Subpart W and Relationship to Current Regulations

40 CFR part 152 currently contains regulations pertaining to the registration of pesticide products, including antimicrobial pesticides. Part 152 contains appropriate definitions and criteria for determining whether a product is a pesticide that must be registered (subpart A); exemptions from FIFRA requirements (subpart B); procedures for applying for registration (subpart C); data compensation procedures (subpart E); the Agency's review of an application (subpart F); fees for applications (subpart U) (currently suspended), and criteria and procedures for classifying a pesticide for restricted use (subpart I). Most of these provisions are unaffected by changes in FIFRA that target antimicrobial program reform measures, and will continue to apply to antimicrobial products as well as other pesticides.

However, FIFRA sec. 3(h)(3)(A) requires that EPA propose procedural regulations focussing on antimicrobial pesticides. Because the statutory reform measures are designed to implement specific goals directed at antimicrobial products only, EPA proposes to create an entirely separate subpart devoted to antimicrobial registration procedures. Proposed new subpart W, entitled "Registration of Antimicrobial Products," would be a freestanding subpart describing the application and Agency review procedures mandated by FIFRA sec. 3(h).

1. **Relationship of subpart W to other subparts in part 152.** Subpart W

would supersede subpart C of current part 152 for antimicrobial products only; subpart C would continue to apply to all other products.

In addition, subpart W---for antimicrobial products only---would supersede certain individual sections of subpart F, *Agency Review of Applications*; subpart F would continue to apply to all other products. Specifically, the following sections would be superseded:

a. § 152.104, *Completeness of applications.* Completeness of applications covered by subpart W is contained in § 152.450, *Contents of application.*

b. § 152.110, *Time for Agency review.* Review periods for applications covered by subpart W are contained in § 152.457, *Review period for applications.*

c. § 152.115, *Conditions of registration.* Conditions of registration for products covered by subpart W are contained in § 152.459, *Terms and conditions of registration.*

d. § 152.117, *Notification to applicant.* Notification of Agency decision on an application is contained in § 152.455, *Action on applications.*

e. § 152.118, *Denial of application.* Denial of an application covered by subpart W is also included in § 152.455, *Action on applications*, although the procedures for denial in § 152.118 are cross-referenced in § 152.455.

As described in § 152.440, all other subparts of part 152 would continue to apply to products covered by subpart W and other pesticides. Some minor modifications are proposed to current § 152.1 to properly refer to the antimicrobial subpart. If subpart W and subpart F conflict for an antimicrobial product or application, § 152.440 states that subpart W would take precedence.

2. **Requirements duplicated in subpart C and subpart W.** To be comprehensive, avoid confusion for users, and avoid cross-referencing unnecessarily, EPA has repeated in subpart W certain elements of its current registration regulations from subpart C. In so doing, EPA has made minor editorial changes not requiring proposal for clarity and organization. EPA has captured the content of the following sections in subpart W, and is not requesting comment at this time:

a. § 152.40, *Who may apply*, which also appears as new § 152.443.

b. § 152.42, *Application for new registration*, which has been incorporated into new § 152.443.

c. § 152.43, *Alternate formulations*, which also appears as § 152.444,

unchanged.

d. § 152.44, *Application for amended registration*, which is also incorporated into new § 152.443.

EPA has incorporated into proposed § 152.443(e) a general provision for certification programs at the Agency's discretion and direction. Current regulations in § 152.44(b)(2) allow a certification submission, in the Agency's discretion, which EPA has typically used only for Agency-directed actions. EPA has not to date expanded the certification option to a class of actions submitted on the applicant's initiative. EPA believes that it may implement certification programs administratively without regulations. Nonetheless, in light of the statutory provision requiring consideration of a certification process, EPA proposes a broader, but still discretionary, use of certification programs. Under today's proposal, EPA could identify elements of an application that the Agency believes are amenable to a certification mechanism. EPA would issue a guidance document (typically a notice to registrants) that would detail how a certification program would be used.

B. Applicability of Subpart W

The applicability of subpart W is governed by the statutory mandate of FIFRA sec. 3(h) in the first instance. However, because of differences in scope between the statutory mandate and the Agency's administration of the antimicrobial program, EPA proposes a broader applicability than is provided for by the statute. This unit explains why certain products would be covered by subpart W and others would not be.

1. Antimicrobial pesticides and food/feed use antimicrobial products are covered by subpart W. Although this proposal reflects the mandate of FIFRA to address "antimicrobial pesticides," EPA has chosen to cover a broader range of antimicrobial products than mandated. It makes sense for these procedural regulations to mesh as closely as possible with the Agency's organization and administration of the antimicrobial program, so as not to cause confusion either within the regulated community or within EPA itself. EPA has created an Antimicrobial Division within the Office of Pesticide Programs, whose responsibilities extend to all antimicrobial products, not just those defined as "antimicrobial pesticides."

Accordingly, EPA proposes that subpart W would apply to both "antimicrobial pesticides," as defined by FIFRA sec. 2(mm) and antimicrobial products that are food/feed use pesticides, but are not defined as "antimicrobial pesticides" by FIFRA sec. 2(mm). Virtually all products in these two categories are processed within the Antimicrobial Division. The procedures and requirements of subpart W would be applied equally to these two categories of products (with the exception of review periods).

2. Wood preservatives and antifouling products are not covered by subpart W. This subpart would not apply to any product that is neither an " antimicrobial pesticide" as defined by FIFRA nor a food/feed use antimicrobial product. Inclusion in this subpart would complicate the registration process for products not processed in the Antimicrobials Division, which are subject to the registration procedures of subpart C.

The status of wood preservatives and antifoulant paints is complicated under FIFRA. FIFRA is very specific in defining certain types of products as antimicrobial pesticides and excluding other, similar products, depending upon the type of claims made for the product. A wood preservative or antifoulant paint that makes only an antimicrobial pesticidal claim is an "antimicrobial pesticide" and would be covered by subpart W as an antimicrobial pesticide. By contrast, any multi-claim wood preservative or antifoulant paint is not an "antimicrobial pesticide" and would not be covered by subpart W. As a practical matter, because most antifoulant paints assert non-antimicrobial barnacle claims, they would not be covered by subpart W. Likewise, many wood preservatives make insecticidal or fungicidal claims and would not be covered by subpart W.

Under FIFRA sec. 3(h)(3)(E), certain wood preservative products that would not be covered by subpart W may nonetheless be eligible for the same review periods as antimicrobial pesticides that are covered by subpart W (see Unit VIII.H. for a full discussion of this provision). EPA's responsibility for wood preservative products that qualify under section 3(h)(3)(E) is fulfilled by ensuring that the statutory review period is met. EPA need not, and does not propose to, make subpart W apply to these products merely to implement the statutory review periods.

Because the status of wood preservatives and antifoulant paints is complex, EPA is providing in Table 1 a summary of the status of these products. The table breaks down wood preservatives and antifoulant paints by type of claim (or combination of claims).
Column 1 of the table lists the claim or combination of claims possible; Columns 2, 3 and 4 answer the questions posed at the top of each column.

TABLE 1--STATUS OF WOOD PRESERVATIVES AND ANTIFOULANT PAINTS

	Is this product an " antimicrobial pesticide"?	Will this product be subject to this proposal?	Is this product eligible for statutorily-required review periods?
WOOD PRESERVATIVES			
Insecticide claims only	No	No	No
Fungicide claims only	No	No	No

Antimicrobial claims only	Yes	Yes	Yes
Insecticide and Fungicide claims	No	No	No
Antimicrobial and Insecticide claims	No	No	Yes
Antimicrobial and Fungicide claims	No	No	Yes
Antimicrobial, Insecticide and Fungicide claims	No	No	Yes
ANTIFOULANT PAINTS			
Insecticide claims (barnacles) only	No	No	No
Antimicrobial claims only	Yes	Yes	Yes
Antimicrobial and Insecticide claims	No	No	No

3. Applicability is not dependent on where a product application is processed. EPA has chosen to extend the proposal to food/feed use antimicrobials for practical organizational reasons. However, EPA emphasizes that where a product application is reviewed does not in any way determine whether subpart W applies. For example, the Antimicrobial Division currently reviews most antifoulant products, that for the most part are not covered by subpart W. The Antimicrobial Division also reviews those wood preservatives that do not make insecticidal claims, some of which are covered by subpart W. This allocation of products may change based upon workload and resource needs.

EPA may, in its discretion and for its convenience, choose to treat products that are not covered by subpart W as if they were covered. For example, EPA currently reviews applications for non-covered products within the review periods of § 152.457, but, except for the narrow class of wood preservatives discussed above, the Agency is not required to do so, and would not be subject to any consequences if it failed to meet a review period.

C. Definitions

Section 152.442 contains definitions that apply to subpart W. Relatively few definitions are needed here, since most terms are defined elsewhere, either in FIFRA itself or in part 152. Terms pertaining to antimicrobial levels of activity (e.g., sterilant, disinfectant) are defined in subpart W of part 156, because they are used in conjunction with labeling and not with registration procedures. Comments are solicited on any additional terms that should be defined in subpart W to inform or clarify the subpart.

Proposed § 152.442 defines the following terms:

1. The term "clearance" is proposed to refer to all types of clearances required under a regulatory authority other than FIFRA before a product may be marketed. The term encompasses food tolerances, exemptions and food additive regulations under FFDCA sec. 408 and 409, and FDA clearances for medical devices under FFDCA sec. 510.

2. The term "complete application" is the general definition describing an application that may be placed into formal review. A complete application is one that contains all elements described by § 152.450, but not necessarily all information required for approving a registration or amendment.

3. The terms “major new use,” “substantive amendment,” and “minor amendment” are proposed as concise terms for application types defined in rather longer phrases in the statute.

D. Types of Applications

1. What the statute requires. FIFRA sec. 3(h)(2) establishes review period goals for antimicrobial applications, shown in Table 2 below, and requires in section 3(h)(3) that EPA differentiate in its regulations the types of review undertaken for antimicrobial pesticides. As discussed in Unit IV.C., EPA intends that defining these application types in this proposal, coupled with EPA's part 158 proposal, will serve to adequately differentiate the types of review undertaken by the Agency. EPA proposes in § 152.445 to define application types that correspond to the statutory review period goals prescribed in the statute. The categories EPA proposes are discussed in this unit.

TABLE 2--STATUTORY APPLICATION CATEGORIES AND REVIEW PERIODS

Description of Application Type	Review period goal	
	Days	Months
Product containing a new active ingredient	540	18
Product that is identical or substantially similar (to another registered product)	90	3
Other new product	120	4
A new antimicrobial use of a registered active ingredient (either a new registration or an amendment)	270	9
Other amendment that does not require scientific review of data	90	3
Other amendment that requires scientific review of data	90 - 180	3 - 6

2. Applications requiring FFDCA clearance. The review periods for which application types must be described apply only to antimicrobial pesticides as defined in FIFRA sec. 2(mm). That definition excludes food/feed use products that require a clearance under the FFDCA. Before assigning an application to a category having a review period, EPA must first exclude any application for a food/feed use that requires a new or revised clearance under FFDCA.

All other antimicrobial pesticide applications fall into one of the categories, described in proposed § 152.445(b) for new registrations and proposed 152.445(c) for amendments to existing products.

3. Current application categories. Currently, EPA does not define types of applications for registration by regulation, but has a detailed tracking system (the Pesticide Regulatory Action Tracking System or PRATS) for actions of all types flowing through the pesticide review process. The system works by assigning action codes to each type of action for purposes of PRATS tracking, reporting and process management; the action code definitions are detailed and do not correlate exactly with the six described in the statute. The PRATS system describes application types and assigns target review periods based on features that are not addressed by the general descriptions in the statute, including:

a. The applicant's method of support for the application (eligibility for the formulator's exemption, for example).

b. The amounts and types of data that require scientific review (product chemistry or confirmatory efficacy data, for example, require minimal review, while toxicology studies require considerable review time).

c. In the case of amendments, what aspect of the registration is being amended (composition, labeling).

d. Whether the application is an initial submission or a resubmission following a rejection of an initial application.

Moreover, combinations of registration actions (for example, a change in composition and labeling simultaneously, each with supporting data requirements) complicate EPA's task of describing a categorization scheme in simple terms.

It would be costly and inefficient for EPA to develop and manage separate tracking systems for antimicrobial decisions and other registration decisions. Nor does it make sense to do so. If EPA is to successfully manage the review process and track review periods for antimicrobial applications, it must use its existing tracking system. Accordingly, EPA's approach to defining types of antimicrobial applications was to crosswalk the types of applications defined by the statute with the descriptors used in PRATS. EPA first sorted the categories of actions in PRATS and identified those that should be included in one of the 6 statutory categories. EPA then fleshed out the statutory descriptions using the greater detail of PRATS action code descriptions for purposes of this proposal. The results of this approach are presented in proposed § 152.445.

4. Terms defined for this proposal. EPA proposes to define more concise terms than the statutory ones for the purposes of this rule. EPA proposes the following terms: (1) the term ”major new use” for the statutory term “new antimicrobial use of a registered active ingredient”; (2) the term “substantive amendment” for the statutory term “amendment to an antimicrobial registration that requires scientific review of data”; and (3) the term “minor amendment” for the statutory term “amendment to an antimicrobial product that does not require scientific review of data.”

5. Single category. Because each antimicrobial pesticide application type will have a prescribed review period under FIFRA, and EPA's failure to issue a decision within that review period will be judicially reviewable, each application must be assigned to a single application category. Ideally, the applicant and EPA would have a common understanding of the designation of an application to avoid disputes over the review period. In all situations, the application categories in proposed § 152.445 are discrete, that is, there is only one possible application type that logically should apply. An application either is for a new registration or is an amendment to an existing registration. Beyond that broad division, the categories may be less well understood and subject to disagreement. Under proposed § 152.445(a), EPA would determine the appropriate category.

There is one situation in which the statutorily designated review period cuts across the application types as defined in the proposal. The Act sets a review period

of 270 days for a “new antimicrobial use of a registered active ingredient” or “major new use.” Proposed § 152.445 defines application types in the first instance according to whether they are submitted to EPA as applications for new registration or amended registration. In the construct of the proposal, therefore, an application for a “major new use” may be either an application for new registration that includes a major new use, or an application for amended registration to add a major new use. Accordingly, both § 152.445(b) and 152.445(c) include a separate category for “major new use.” In both cases, the review period would be 270 days.

6. Applications for new registration. a. A product containing a new active ingredient. Products containing new active ingredients are a well-understood category. An application that proposes the registration of an active ingredient that has never before been registered falls into this category. A product containing a new active ingredient typically requires review of considerably more data than one containing already registered active ingredients.

b. A product bearing a major new use. This category consists of an application for new registration of a product bearing a major new use. A major new use is any use that is not registered for one or more of the active ingredients in a product. Typically a major new use would involve a significantly different pattern of use that changes or increases the exposures to the active ingredient, such that substantial amounts of new data are required to evaluate the different or incremental risks presented. This definition is comparable to that in § 152.3 for "new use" for non-antimicrobial products.

EPA intends in its part 158 proposal to categorize all antimicrobial uses into one of the following 12 use categories. All currently registered antimicrobial use patterns are included in one of these larger use classifications for data requirement purposes, but EPA has not to date classified the existing use patterns in this organized fashion.

(1) Agricultural premises and equipment
(2) Food handling/storage establishments premises and equipment
(3) Commercial, institutional and industrial premises and equipment
(4) Residential and public access premises
(5) Medical premises and equipment
(6) Human drinking water systems
(7) Materials preservatives
(8) Industrial processes and water systems
(9) Antifouling coatings
(10) Wood preservatives
(11) Swimming Pools
(12) Aquatic areas

Some categories would be further divided into subcategories. Subcategories would generally be defined on the basis of similar exposures and data requirements.

Examples of significant use/exposure differentials among use categories and subcategories are food/non-food use and indoor/outdoor use or exposure.

Using these categories and subcategories of antimicrobial use patterns, EPA would regard as a major new use of an antimicrobial active ingredient any use in a different use category or subcategory from currently registered uses for that active ingredient. As an example, an active ingredient is registered with uses in the category of "Materials Preservatives" and subcategory "Indoor non-food uses." If a registrant proposed a new use either in that same category for an "Indoor food use" (a different subcategory), or in the different category of "Residential and Public Access Premises," that application would be a major new use of that active ingredient.

c. A product that is identical to an existing product. For clarity, this proposal separates "identical" and "substantially similar" products into two categories, even though they have the same review period. Applications for end use products of these types are generally indistinguishable from the so-called "fast-track" applications of FIFRA sec. 3(c)(3).

Identical products are those that have an identical composition to another registered product and bear identical use patterns. Both active and inert ingredients must be identical and in exactly the same proportion as the existing product. In the universe of antimicrobial products, "identical" products include products that are formulated by one company and simply repackaged by another company. These so-called "repacks" must be separately registered by the repackager. Identical products also include those that are actually formulated by a second producer based upon specifications provided by another registrant. The significant difference between these two types of identical products is that "repacks" require virtually no data for registration, while those that are produced separately require certain minimal "bridging" data to ensure that they are actually identical in composition and efficacy.

Identical use patterns mean that the label does not deviate in terms of organisms controlled, use sites, or directions for use. An applicant's product may have fewer (but identical) claims than another registered product and still be an "identical" product, but may not have different or expanded claims.

d. A product that is substantially similar to an existing product. Substantially similar products are those that are permitted to have minor differences in three areas--composition, use pattern, or method of data support--from another registered product. When evaluated against another identified registered product, a "substantially similar" product must have the same active ingredients as the claimed similar product, in substantially the same proportion. The inert ingredients must also be substantially similar in chemical composition and functionality to the claimed similar product. For example, emulsifiers, fillers, solvents, propellants, etc., in the applicant's product must have similar counterparts in the cited registered product so EPA can reasonably conclude that both formulated products will have essentially the same chemical and physical characteristics and toxicity profile. Because substantial similarity

may depend on the characteristics of the individual products or the active and inert ingredients, decisions on similarity would be made on a case-by-case basis.

Substantially similar use means that the product bears a use pattern similar to the claimed product. Again, fewer use patterns do not make the product dissimilar, but adding or changing use patterns would exclude the applicant's product from treatment as a substantially similar product. A use pattern is a claim for control of a specified organism on a specified site under specified conditions of use. With respect to public health products, for which efficacy considerations are paramount, use sites must be carefully considered in relation to the pest organism, and small formulation changes or variations in use directions can mean the difference between an efficacious product and a non-efficacious product. For this reason, "substantially similar" use patterns for public health products would be limited to identical organisms on both products. For non-public health products, substantially similar use patterns could involve organisms that are similar but not identical.

A similar method of data support means that the applicant is using methods of data support that do not require EPA to evaluate data (other than product chemistry data) to review the application. As a practical matter, this means that the applicant is either citing all required studies or requesting a waiver of required studies. Many antimicrobial products must be supported by efficacy data of some sort. Such products are not substantially similar even if they are similar in composition and use pattern to another product, because the submitted efficacy data must be reviewed by EPA. Such products would be considered “other” products.

e. "Other" products. All applications for new registration other than new chemicals, identical or substantially similar products or those bearing a major new use, would be assigned to the "other" category. These are products which have significant differences in composition, uses, method of data support or labeling. Proposed § 152.445(b)(5) provides examples of applications that would be categorized as "other" new applications, but is not comprehensive or explicit, since it is essentially a default category of application. If a new application cannot readily be categorized either as a "new active ingredient" or as an "identical" or "substantially similar" application, it would routinely be placed in this category.

7. Applications for amendment. Applications for amendment to an existing registration are categorized in much the same fashion as new applications, that is, by defining the ends of the review spectrum, and placing all amendments not clearly delineated into a middle category. EPA therefore defines in this proposal three categories of amendments.

a. Amendment to add a major new use. As noted earlier, a major new use may be presented to EPA in the form of a new registration or an amendment. This category is for amendments to add a major new use to an existing registration (as opposed to a new registration that bears a major new use). “Major new use” would be the same as described earlier.

b. Minor amendment. At the other end of the amendment spectrum, EPA proposes an application category termed “minor amendment.” This category is intended to parallel the "identical or substantially similar" category for new applications, and is also identical to the statutorily-defined "fast-track" provision of FIFRA sec. 3(c)(3). In no case would a minor amendment require the review of any data. The examples in proposed § 152.445(c)(3) list minor amendments not in terms of the actual registration changes that might be proposed, but in terms of the nature of the evaluation that EPA must do. EPA does not believe that this proposal can, or needs to, describe all the possible types of "minor amendments."

The following are some characteristics of a minor amendment:

* The evaluation can be conducted entirely within a Product Manager team, without any scientific consultation.
* The decision relies only on non-technical, non-scientific information readily at hand.
* The decision requires only regulatory or administrative judgments, not scientific ones.
* The decision applies existing policy, evaluates adherence to existing policy, or ensures consistency among decisions.
* The evaluation consists of simple comparisons among products.
* The evaluation requires no separate documentation (such as a scientific review) beyond the decision itself.

b. Substantive amendment. EPA proposes a category termed "substantive" amendments. This type of application would parallel the "other" category of new registrations, and would encompass all amendments that are neither "major new uses" nor "minor" amendments. This category consists of amendments that require the review of any scientific data.

Most changes in label precautionary statements or use directions are included in this category, as well as many changes in product composition. Inclusion of such a wide variety of amendments in this category simply reflects the fact that these changes require the review of some data. The data may consist solely of bridging or confirmatory chemistry, toxicity or efficacy data to demonstrate that the product and its uses, as modified, would not significantly increase risks, or that the product as modified remains efficacious. Moreover, the review may be a cursory evaluation of existing data to determine that the amendment is adequately supported. Nonetheless, the defining characteristic of a substantive amendment is the need to review some data, either submitted by the applicant or cited from Agency files.

This category is the only one in the statute that carries a range of review periods (90 to 180 days), a provision that recognizes the variety of amendments that can conceivably be proposed to a registration. Arguably, the inclusion of a range of review periods suggests that there are gradations of application types within this

range--applications that are relatively less complex that could fall at the short end of the review period (90 to 120 days) and others that require the full 180 days. Under this interpretation, EPA could be expected to establish by regulation subcategories of application to which a specific review period within the 90 to 180 day range would apply. Equally consistent with the statute would be an interpretation holding that the range was included simply to allow EPA the flexibility to deal on a case-by case basis with the wide variety of amendments covered by this category, and that no further differentiation or other regulatory treatment is required.

EPA adheres to the latter view. EPA does not believe that it is statutorily obligated to establish subcategories of 90- to 180-day substantive amendments. EPA has not discerned any great benefit to the Agency in doing so, especially by regulation, while noting a number of disadvantages. A proliferation of categories in itself creates administrative burdens for EPA in tracking applications. The more categories that are created--each having its own description against which applications must be judged and a distinct review period--the more time it takes EPA generally to administer a tracking system and ensure that review periods are met. Likewise, the more EPA is bound by regulatory categories and review periods, the less flexibility the Agency has to respond to changing review needs or critical priorities without running afoul of its regulations. Moreover, it is not clear that there would be significant benefits to applicants in gaining a decision 30 to 60 days earlier that would justify the additional administrative burden for EPA. EPA is not precluded from adopting administrative subcategories if it does not choose to adopt regulatory ones. Accordingly, EPA is not proposing any specific subcategories. Under today's proposal, all substantive amendments would be afforded the same review period, that is, a maximum of 180 days.

In its stakeholder meetings over the past year, however, industry representatives requested that EPA solicit comment on whether subcategories should be established. Suggestions from the Chemical Specialties Manufacturers' Association (CSMA) included the following, all of which would be classified as substantive amendments:

1. Amendment with data to add a "me-too" use that requires full toxicology and efficacy review.

2. Amendment with data to change a formulation that requires full toxicology and efficacy review.

3. Amendment with data to modify a label requiring a toxicology or efficacy review.

4. Amendment without data to modify a label which requires a toxicology or efficacy review.

EPA solicits comments on these and other sub-categorizations and review periods. Commenters should consider the following factors important to EPA's decision:

* A suggested category must be capable of unambiguous description. EPA would likely not consider a category of uncertain description that could be subject to dispute between applicants and the Agency.

* A suggested category must be meaningful in terms of both numbers of applications likely to fall in that category and in the suggested shorter review period. A category that includes relatively few amendments would be equally unsatisfactory as one that includes too many amendments. A suggested review period with less than a 30-day decrement (180 to 160 days for example) would likely not be considered meaningful. Nor would EPA likely adopt a category with a suggested review period of 90 days, since there would then be no distinction between that subcategory of substantive amendment and a minor amendment.

*A suggested category must be comprised of amendments that can be reviewed within a review period of less than 180 days without jeopardizing EPA's ability to meet other review periods. EPA is committed to making decisions on applications as rapidly as possible, and currently is meeting the review period goal of 180 days consistently for all substantive amendments, but without consideration of subcategories.

If commenters convince EPA that additional subcategories should be established, and that the benefits of less than 180-day decisions outweigh the added administrative burdens (bearing in mind that the Agency has limited resources and that additional administrative burdens mean fewer resources for reviewing applications), EPA may in the final rule adopt one or more subcategories of substantive amendments that would refine the review period within the 90 to 180 day range. EPA will not consider subcategories of any types of applications other than substantive amendments.

E. Consultations During the Application Process

Because EPA is required to process complete applications for registration within judicially reviewable timeframes, it is critical that applications and data be complete and conform to Agency requirements, and, as much as possible, that applicants and the Agency have a common understanding of requirements and expectations about the process and its outcomes.

EPA recognizes that the registration process can be complicated for persons who are unfamiliar with FIFRA and its requirements; even for those who deal routinely with the Agency, keeping up with new policies and procedures can be challenging.

In the past, deficiencies in applications or data have been resolved during or after the review process, either informally, for example with a telephone call for a minor problem, or formally, by rejecting an application with significant deficiencies. The current review process has tended to encourage consultation only after an application has been rejected, when EPA can explain both the results of its review and what an applicant needs to do to correct deficiencies. Pre-submission consultation has not

typically been the case with antimicrobial products.

With the completeness of an application at stake for an applicant, and strict review periods in place for EPA, it makes sense for both to consult as much as is practicable and as early as possible. Misunderstandings about requirements and expectations may lead to needless determinations of incompleteness or denial for the applicant, while impeding EPA's ability to reach decisions in a timely fashion as required by the statute.

EPA encourages consultation with the Agency on any application prior to a determination of completeness. However, the majority of antimicrobial applications are for so-called "me-too" products and uses, those which are identical or substantially similar to others already registered. Such applications are relatively easy to submit correctly, seldom raise new or controversial issues, and should not routinely require specific consultation. Once an application has been determined to be complete, and has been placed in review, the applicant should not need or expect to consult the Agency until the end of the appropriate review period (which for “me-too” products is only 90 days), or until EPA notifies the applicant of a deficiency.

However, EPA has identified two areas where it believes advance consultation is essential to the submission of a complete application, and proposes in § 152.447 to require pre-submission consultation. The first is applications for new chemicals and major new uses. These consultations, which are common for agricultural chemicals but rare for antimicrobial chemicals, help the applicant and the Agency agree upon data requirements, data waivers, or issues that typically arise for new chemicals and major new uses (such as food use status).

In addition, EPA proposes to require pre-submission consultation whenever an efficacy test protocol or method must be approved by the Agency either because there is no protocol or because the applicant wishes to modify an existing protocol.

The regulation does not prescribe how consultation is to be accomplished. There is no requirement that a required consultation occur in a meeting; a conference call, letter, or other form of communication may be sufficient, depending on the nature of the new chemical, new use, or protocol approval needs. However, proposed § 152.447 emphasizes that any regulatory determinations must be in writing. EPA expects the applicant to follow up any consultation with a summary of any decisions so that EPA may confirm them in writing. Proposed § 152.450 would require written documentation of a consultation describing the substance of the consultation to be submitted with the application to verify that the consultation took place as required.

In turn, EPA would commit to adhere to the decisions agreed upon in a pre-submission consultation unless the circumstances of the application change, its determinations were in error, or a question of adverse effects arises.

F. Contents of Applications

1. What the statute requires. FIFRA sec. 3(h) requires formal Agency review only upon submission of a "complete" application, and requires that EPA clarify its criteria for completeness of an application. Current regulations in 40 CFR 152.50 describe the contents of an application for registration, including applications for antimicrobial products. EPA proposes in subpart W an expanded and more detailed description of the contents of a complete application, including some new elements of an application not currently required.

2. Definition of complete application. First, EPA is proposing a general definition of "complete application" in § 152.3, a definition that would apply to all applications for registration. Other provisions of FIFRA also link Agency priority, review or action to completeness of an application, for example, the fast-track and minor use provisions of section 3(c)(3), and the expedited review provisions of section 3(c)(10). The general definition is repeated in § 152.442 to apply to antimicrobial applications.

The definition draws a distinction between the completeness of the application itself (which allows EPA to commence formal Agency review), and the completeness of the information needed for EPA to approve the application. It is relatively easy to define a core set of items--forms, labels, routine and uncomplicated data--which, if present in an application, suffice to begin review. But completeness for Agency decision purposes encompasses an element of "adequacy" that, for many applications, can only be determined on a case-by-case basis, and only during or after substantive review of the application. Accordingly, the decision by EPA that an application is "complete" (and, for “ antimicrobial pesticides,” that begins a review period), represents only a preliminary or interim determination of overall completeness intended to allow EPA to initiate formal review.

Completeness becomes a question of adequacy as the amount of scientific data and the complexity of the risk assessment increase. Typically, applications for new chemicals or new uses, and actions involving food uses or increased non-dietary exposures require more data. FQPA significantly expanded the scope of dietary risk assessment under the FFDCA, particularly for infants and children. Correspondingly, EPA will be enhancing its non-dietary assessment of risks to infants and children, such as might occur with antimicrobial pesticides. However, "fast-track" or "me-too" applications that require little or no scientific review comprise the bulk of antimicrobial applications submitted to EPA. These actions are relatively straightforward as to application and approval criteria and EPA expects that the completeness determinations for review purposes and for approval of the application generally would be equivalent. For these types of applications, EPA would be less likely to find during its formal review that it requires data or information beyond that provided at the time of application.

3. Contents of an antimicrobial application. FIFRA sec. 3(h) requires that, in

its final regulation, EPA clarify criteria for determination of the completeness of an application for antimicrobial pesticides. EPA is proposing in § 152.450 detailed requirements for applications, which, if satisfied, would allow a preliminary determination of completeness.

Current requirements in § 152.50 form the basis for the requirements in proposed § 152.450, but EPA proposes an expanded level of detail. Table 3 below sets out each element of an antimicrobial application as proposed today. Column 1 identifies the application requirement. Column 2 gives the reference in proposed § 152.450 of the requirement. Column 3 gives the cross-reference to § 152.50, or indicates that the requirement is new. New elements are discussed more fully afterwards. Column 4 provides explanatory notes, indicating that a requirement is unchanged from current requirements, or describing additions or changes for antimicrobial applications.

TABLE 3--CONTENTS OF AN ANTIMICROBIAL APPLICATION FOR REGISTRATION

Requirement	§ 152.450 reference	§152.50 reference	Explanatory notes/differences for antimicrobial applications
Application form	(a)	(a)	Unchanged. Detail is provided on the elements and completeness of the form.
Authorization for agent	(b)	(b)(3)	Unchanged.
Summary of application	(c)	(c)	Unchanged. This summary and that required for results of studies may be consolidated.
Statement of formula	(d)	(d) (f)(2)	Unchanged. The Statement of Formula includes both product identity and composition.
Draft labeling submission	(e)	(e)	Unchanged. Detail is provided on the presentation and completeness of the labeling submission.
Method of support documentation	(f)	(f)(1)	Unchanged. Consists of forms and information required to demonstrate compliance with data compensation requirements of FIFRA. § 152.450 summarizes the existing methods of data support.
Data	(g)	(f)(2) (c)	Unchanged.
Adverse effects information	(h)	(f)(3)	Unchanged. The proposal clarifies that such information is not required with an application for amendment.
Tolerances or other food clearances	(i)	(i)	Unchanged.
Consultation documentation	(j)	New	If a pre-submission consultation occurred under § 152.447, or decisions or agreements were made at an optional consultation, the applicant would be required to provide documentation of that consultation.
Data reviews conducted by other regulatory authorities	(k)	New	If reviews have been, or are being, conducted by other regulatory authorities, the applicant would be required to submit those that are available.
Other clearances	(l)	Not previously in regulatory form	Unchanged. Applicants are currently required to provide evidence that the applicant has requested clearances required by other Agencies.
Packaging	(m)	(g)	Unchanged. Clarifies that packaging itself is not to be submitted with an application unless specifically requested by EPA.
Product samples	(n)	Not previously in regulatory form	Unchanged. Clarifies that product samples are not to be submitted with an application unless requested by EPA.
Self-addressed means of EPA notification	(o)	New	Voluntary submission of a postcard or other means for EPA to notify the applicant of a preliminary determination of completeness.
Fees	(p)	Part 152, subpart U	Unchanged. Application fees are currently suspended. Included here only for completeness.

Authorization to share data and data reviews	(q)	New	Optional. The applicant is requested to authorize EPA to share either data or EPA reviews of data with State, Federal, national, or international regulatory authorities.

4. New required elements of applications. Only three required elements of an application are entirely new in today's proposal.

Proposed § 152.450(j) would require that applicants submit documentation of the results of pre-submission conferences, either those required by § 152.447 or optional ones, at which regulatory-related decisions were discussed or agreements reached. The documentation could be minutes of the meeting that EPA has reviewed, or could be a letter from EPA confirming the decisions reached or approving a specific test regimen or protocol.

Proposed § 152.450(k) would require the applicant to submit available reviews of the application, or of individual studies, that have been conducted by other regulatory agencies or organizations. If an application has been submitted for regulatory review elsewhere, the applicant would be required to inform EPA of that fact. Applications may have been submitted concurrently to other national regulatory bodies, or to Federal Agencies or States. If EPA is able to use the results of reviews conducted elsewhere, it will save time and resources in reaching a decision on the application, which may allow earlier entry into the marketplace. An applicant would not be required to either await the results of ongoing reviews or to specifically obtain copies of the reviews to submit with his application. However, if reviews have been provided, the applicant would be required to submit them to EPA with his application. This provision is intended to complement and mesh with efforts by the Organization for Economic Cooperation and Development to create an international standardized “dossier” system for pesticide information submission.

Proposed § 152.450(l) would require that applicants provide EPA with documentation that they have received (or have applied for) any other clearances from Federal agencies that might be necessary to market or use the product. EPA currently requires such documentation before issuing a registration bearing the use in question. Submission with the application of evidence that the clearance has been requested or obtained would help assure EPA that the applicant is fully aware of its obligations under other laws. Ensuring that all regulatory clearances are underway concurrently also makes the review periods for EPA meaningful. EPA approval of an application within a review period would have little meaning if the applicant cannot market the product or users cannot use it because additional clearances are needed.

5. Non-mandatory or clarified elements of applications. Four further elements of the antimicrobial application are either clarified by inclusion of explanatory language, or are voluntary information.

Proposed § 152.450(m)(2) clarifies that product packaging is not to be submitted unless requested. The submission of labeling is accomplished using draft typescript copies or mock-ups that are suitable for microfilming and filing.

Proposed § 152.450(n) clarifies that applicants are not to submit actual product samples with an application unless requested. EPA typically requires samples of active ingredients or analytical standards in conjunction with setting tolerances. EPA may also request samples of antimicrobial pesticides bearing public health claims for EPA evaluation of efficacy. In each case, EPA will separately request such samples and instruct the applicant how and where to provide them.

Proposed § 152.450(o) provides that applicants who wish to be notified whether an application is preliminarily complete (and therefore has been placed into review with a review period) furnish EPA with a means of notifying them. This could take the form of a postcard, form letter or other means of such notification. Without an easy means of notification, EPA cannot commit to written notification. Nor will EPA use notification methods such as telephone or e-mail that cannot properly be documented by an authorized signature as EPA-originated, although advances in technology may make this feasible in the future. Finally, EPA would notify the applicant only at the time the application is determined to be complete; at that time the formal review period would have started, and EPA's next communication with the application would normally be a decision on the application (§ 152.455, *Action on applications.*) EPA would not accept multiple postcards or requests simply to advise the applicant of the status of the application review during the review period.

Proposed § 152.450(q) requests, but does not require, that the applicant provide authorization for EPA to share the data or EPA reviews of data with other regulatory agencies. The ability to share data and reviews among regulatory authorities will contribute to streamlining EPA review processes for antimicrobial products, and is an essential element in achieving harmonization of reviews.

An applicant who intends to market a product in the United States may be required to register the product with individual States; an applicant who intends to market the product abroad (such as in Canada) must meet the regulatory requirements of other countries. While the depth of regulatory scrutiny of a product varies among States and countries, many require the submission of equivalent amounts of data as the applicant has submitted to EPA. The ability to share data submitted to one regulatory authority with others can reduce the paperwork and review burden of all by reducing multiple identical submissions and allowing the sharing of the review load. EPA already is engaging in work-sharing efforts with the State of California and with Canada.

This effort can be complicated by confidentiality claims under FIFRA sec. 10(b) or the disclosure restrictions of section 10(g). Section 10(g) permits the Agency to disclose data in support of registration only to those who affirm that they will not further disclose the information to foreign or multinational pesticide producers. Although a mere claim of confidentiality under FIFRA sec. 10(b) does not conclusively prevent disclosure of information, it does require the Agency to follow certain procedures (which may include obtaining a substantiation of the claim from the registrant) to determine

whether the information is entitled to confidential treatment. These procedures can interfere with free and unimpeded exchange of information and data among regulatory authorities.

On November 27, 1985, EPA issued Class Determination 3-85 (50 FR 48833). EPA declared as non-confidential (and not subject to the disclosure restrictions of FIFRA sec. 10(g)) reviews of data that do not contain information which would disclose: (1) manufacturing or quality control processes; (2) the details of any methods for testing, detecting, or measuring the quantity of any deliberately added inert ingredient of a pesticide product; (3) the identity or percentage quantity of any deliberately added inert ingredient of a pesticide product; (4) unpublished information concerning the production, distribution, sale, or inventories of a pesticide (such information might appear in reviews which discuss the amount of a pesticide sold or used in a given time, and thus might concern the significance of data from a test or experiment); (5) any complete unpublished report submitted to EPA by a registrant or applicant; or (6) excerpts or restatements of any such report which reveal the full methodology and complete results of the study, test, or experiment, and all explanatory information necessary to understand the methodology or interpret the results.

Agency data reviews are normally drafted to avoid inclusion of information that is within the 6 categories described in the paragraph above, but EPA cannot guarantee that all reviews will meet these criteria. Moreover, as discussed above, the Agency may have a need to share raw data in addition to study reviews with States and other countries.

EPA believes it is in the interest of both applicants and the Agency to have free and unimpeded exchange of information and data among regulatory authorities. To that end, this proposal requests that applicants authorize such exchange at the time of application. Sharing data and reviews with other regulatory authorities would not compromise the protection against disclosure provided by section 10, because such sharing would not constitute a public disclosure of the information.

To authorize data- or review-sharing, the applicant would submit a statement authorizing EPA to share either any data submitted with the application or EPA's reviews of such data with regulatory authorities as needed. An appropriate permission statement would be similar to the following:

> This letter grants permission for the U.S. Environmental Protection Agency to share all [data submitted with this application][EPA reviews of data submitted with this application], with State, other U.S. Federal, or other national regulatory authorities. This authorization does not waive any restrictions on public disclosure of the data [reviews].

G. EPA Action on Applications

1. Completeness screens. EPA currently screens all applications for

completeness, not just antimicrobial applications. The Office of Pesticide Programs Front End Processing Unit (FEPU) receives all applications, processes them administratively, and conducts a simple screen to ensure that required application items are present and properly submitted. An application accompanied by data is subsequently screened for submission and format requirements of the data itself. Data submissions must include specific items prescribed by Agency regulations in 40 CFR 158.32 and 158.33, as well as meet format and presentation requirements detailed in PR Notice 86-5. Neither of these screens evaluates the substance of the application or the data. In either the FEPU or data screen, EPA may identify deficiencies that must be corrected. Depending on the nature of the deficiency, the application may be placed into review anyway, and deficiencies corrected during the review process. This informal screening and correction process has served the Agency and applicants well over the years.

Nonetheless, because FIFRA directs EPA to develop completeness criteria, and because antimicrobial pesticides are now subject to review periods which are computed only if an application is determined to be complete, it is imperative that EPA not only establish more formal criteria for completeness, but that EPA conduct a more rigorous completeness screen before determining even preliminarily that an application is complete. Section 152.455 of today's proposal, *Action on applications*, describes what actions EPA may take on complete and incomplete applications.

2. Preliminary determination of completeness. In addition to the FEPU administrative screen and the data review screen, the Antimicrobial Division has instituted a more in-depth screening process to ensure that only applications that meet the standards of proposed § 152.450 enter formal Agency review. The antimicrobial screening process builds on the earlier screens in two ways: by evaluating the adequacy of certain application items that are typically not evaluated in a simple administrative screen (e.g., are clearly required studies included?), and by evaluating application requirements peculiar to antimicrobial pesticides (e.g., efficacy data requirements).

Based on this screen, EPA would make a preliminary determination whether an application is complete (§ 152.455(a) and (b)). If the application is incomplete, EPA would notify the applicant, describe the deficiencies and await resubmission by the applicant. If complete, and a self-addressed notification has been provided in accordance with proposed § 152.450(o), EPA would notify the applicant of the determination, compute the date under proposed § 152.457 when a decision may be expected (calculated from date of receipt of the application), and place the application into formal review. If no self-addressed notification is provided, EPA would place the application into formal review, but would not notify the applicant. Because some elements of completeness cannot be evaluated until the application is reviewed in depth, a determination of completeness sufficient to place the application into formal review must, of necessity, be a preliminary one.

EPA is likely to apply its completeness criteria very strictly, for several reasons. Strict application of completeness criteria appears to be consistent with the statutory direction to base enforceable deadlines on completeness determinations. Further, consistent treatment of applications is more likely if EPA establishes and adheres to relatively "bright line" criteria for completeness. Finally, the sheer number of applications that EPA receives means that it must allocate its review resources very carefully. EPA does not believe it unreasonable to use completeness determinations as a management tool for those resources. While refusing entry into review for a minor deficiency may appear inflexible, it is important to recognize that what is flexibility for one applicant may appear to be inconsistency or inequity to another. EPA believes that lack of completeness criteria and inconsistent application of such criteria have been a source of applicant dissatisfaction.

3. Effect of incompleteness determination on review period. Regardless of when a determination of incompleteness is made, the consequence is the same: the review period would either not be computed or would be halted and recomputed anew upon receipt of all items completing the application. EPA would notify the applicant that the application is incomplete, and specify how it can be made complete.

4. Applicant resubmission. Proposed § 152.455(b) specifies that EPA will deem the review period to have begun only upon receipt of the last item that completes an application. Partial information clearly does not satisfy the completeness criteria, or allow the application to be placed into review. EPA discourages applicants from correcting application deficiencies in a piecemeal fashion; nonetheless, historically this has happened (and been tolerated by the Agency) because some deficiencies are easy to correct (a form not signed, an unreadable draft label), while others may take longer (a missing required study).

An applicant may wish to resubmit rapidly what can be readily corrected, and EPA may wish to accommodate the applicant's desire to begin review of available information. As noted earlier, under the current application review system, both of these can often be accommodated. EPA frequently is requested and agrees to place an application into review while waiting for some item that has not yet been submitted, expecting that the missing item can "catch up" before it is needed for review. Under the tight review periods provided for antimicrobial application review, however, EPA cannot afford the time and resources that may be lost if an applicant fails to provide the needed information in a timely manner. Other applicants also suffer because their applications are not reviewed as promptly as possible. Accordingly, EPA would not place an application into review until all deficiencies are corrected, and a preliminary determination of completeness can be made.

5. Agency review. Once EPA has issued a preliminary determination of completeness, EPA will place the application into substantive Agency review. EPA conducts scientific reviews in parallel as much as possible, although some reviews depend upon the results of others and must be conducted sequentially. Proposed § 152.455(d) specifies that, once in review, EPA will complete all reviews for the

application before issuing a decision of any sort, even a determination that the application remains incomplete. EPA intends, however, to continue, to the extent practicable, its longstanding practice of communicating informally with applicants about interim results of reviews as they are completed. Informal communications are not Agency decisions on the application itself, and are entirely at the Agency's discretion.

6. EPA decisions after review. Section 3(h)(3)(F)(I) provides that:

> [The Administrator shall notify an applicant whether an application has been granted or denied not later than the final day of the appropriate review period under this paragraph, unless the applicant and the Administrator agree to a later date.

This provision is probably the single most significant element of the overall antimicrobial reform effort mandated by FIFRA. All process improvements and efficiencies directed elsewhere in FIFRA sec 3(h) are for the purpose of shortening review periods to the goals specified in FIFRA sec. 3(h)(2). This provision holds EPA to a decision within the review periods that would be established under this proposal. EPA's failure to meet those review periods is judicially reviewable.

EPA takes seriously its mandate for antimicrobial process reforms: meeting its review period goals is the most visible and tangible evidence of the success of its reforms.
Hence, how EPA implements this provision, both in making decisions and in managing the review period process, is critical.

EPA review must culminate in one of two specified decisions--approval or denial--by the end of the review period. The "review period" can be either that established in proposed § 152.457, or an extended review period agreed to between an applicant and EPA. The statute does not provide for negotiated shorter review periods; those that would be established under this proposal are minimum review periods that would apply unless extended by agreement.

The statute is silent on whether EPA may take other unspecified actions prior to the expiration of the review period and what those actions might be, but clearly no action other than approval or denial is authorized at the end of the review period. EPA believes that it is within its discretion to take interim actions prior to the expiration of the review period, as long as the final decision on an application is either approval or denial. Interim actions might include communications with applicants on the application, preliminary indications of incompleteness or other deficiencies that might lead to denial, or notice of the Agency's intent to approve the application.

Approval is of course the desired decision from the applicant's point of view. If the application is complete and relatively uncomplicated, taking that action within the review period is mostly a function of efficient management of the review process. The bulk of the antimicrobial applications that EPA receives are for so-called "me-too" products and amendments (those with review periods in the range of 90 days). These can be fairly characterized as uncomplicated, and problems with completeness are

more likely to be the reason for delays in approval than the complexity of the review or decisionmaking processes. Delays due to incompleteness are not included in EPA's review period. A rigorous application of the completeness criteria of proposed § 152.450 to weed out incomplete applications should enable EPA to reach a decision within the review period for applications that are complete.

For applications of greater complexity--new chemicals, major new uses and other products and uses that are not substantially similar--the decision process is not a straightforward one-time review leading to a single decision point of approval or denial. Rather it involves a series of decisions, with stops and starts in the process as the application progresses. Typically, such an application goes through several cycles of review. Under current practice, EPA commences review of an application and often determines that it is incomplete, inadequate, or raises risk or efficacy concerns that must be addressed. The Agency notifies the applicant and places the application into pending status until the applicant responds. The "down time" awaiting applicant response varies considerably based on the type of problem, but if a new study is required, may be from 6 months to 2 years. For the most complex applications, those for new chemicals and major new uses, the cycle may be repeated several times. Thus the total elapsed time from beginning of review to an approval or denial decision may be lengthy, but the length is generally not attributable solely to EPA inaction or delay. The time may be marked by interruptions when the application is awaiting applicant action and not EPA action.

In the current review process, an interim decision is not a denial, which carries the right to administrative appeals. EPA refers to such a decision as a "rejection," a term used to reflect the interim incomplete status of the application and of EPA's review.

The provision in FIFRA sec. 3(h) that EPA must reach a decision within a specified review period is silent on whether or how the review period should accommodate the cyclical nature of the review process, in which EPA review time and applicant response time typically alternate. A strict interpretation of the provision would be that the review period includes applicant "down time."

Congress rightly anticipated that EPA might reasonably need a longer review period in certain circumstances, and the statute contemplates, but does not specify, a process for reaching agreement on a longer period for the formal approval or denial decision. The excepting clause, "unless the applicant and the Administrator agree to a later date," while not perfect in that it does not reflect the reality of the review process, does allow EPA and the applicant, by agreement, to extend the total review period. An agreement on extension could be tailored to account appropriately for applicant "down time," without penalizing EPA or subjecting the Agency to the threat of judicial review. EPA believes that this clause provides much-needed flexibility both in the types of actions that EPA may take and the process by which an appropriate review period is to be agreed upon.

Regardless of the reasons for needing an extension, EPA cannot afford to engage in case-by-case negotiation for every application that might approach the end of its review period without a decision. To reflect more closely the actual review process, EPA needs to be able to take actions before the end of the review period that have the effect of extending the overall review period by stopping it for some period of time. Without such flexibility, EPA may be compelled to use its denial authority more frequently to meet the statutory requirement to issue a decision.

EPA does not intend to violate its regulations by failing to make decisions in a timely manner. If EPA is unable for any reason to issue a decision on an application within the review period, and cannot agree with the applicant on an extension, EPA's failure permits the applicant to seek judicial review. EPA views the judicial process as the least desirable means of resolving disputes over the review period. Not only is it time-consuming and costly for both parties, but a predictable result of judicial review is that a court would order EPA to complete review within some further period of time, an outcome which has the same effect on the review schedule as if EPA and the applicant had agreed to an extension.

EPA's alternative course of action, permitted by the statute, is simply to deny the application. Denial would be governed by the provisions of FIFRA sec. 3(c)(6), which permits an administrative hearing process. While EPA may thereby satisfy the requirement to issue a decision and avoid the threat of judicial review, the Agency believes there is little value added by the administrative hearing process, which can be as protracted, costly and uncertain as judicial review. Nor does EPA believe that applicants, many of whom are small companies without substantial financial or technical resources, are well served by either an administrative or judicial process in this particular context. Their objective is presumably to obtain an EPA decision in the most timely manner and without extraordinary effort or cost on their part.

Given that individual negotiation is not feasible for any large number of applications, that EPA and applicants may reasonably disagree on the need for or length of extension, and that neither judicial review nor denial of the application is an appealing means of resolving such disputes, EPA believes it prudent to establish rules for implementation of review periods that build in provisions for extension. Today's proposal would do so, while not foreclosing the opportunity for case-by-case extension agreements when warranted.

Accordingly, EPA proposes in § 152.455 a series of possible decisions arising from substantive Agency review, incorporating proposals for dealing with extensions. These are: (1) the application may be approved; (2) the application remains incomplete; (3) the applicant has failed to furnish sufficient information to determine whether the application may be approved (two circumstances with different consequences for the review period); and (4) denial for cause.

7. Approval. If EPA approves the application, it would follow its customary procedures to notify the applicant by issuing a Notice of Registration or letter of approval for an amendment and sending back a stamped copy of the approved labeling

if called for.

8. Opportunity for rebuttal. EPA frequently issues a registration that is conditioned upon the applicant's making certain corrections or modifications to the registration before sale or distribution. Such terms and conditions generally only require changes which are minor in nature and most often consist of labeling changes to be consistent with similar products, adhere to Agency policies, or clarify label statements. In EPA's experience, virtually all new registrations require some modification to the label; for this reason EPA requests and approves draft labeling as part of the application, and requires that the applicant submit final printed labeling prior to sale or distribution of the product.

EPA's approval of the registration and permission to distribute or sell the product is premised on the applicant's acceptance of EPA's terms and conditions. Proposed § 152.455(d)(1) would permit applicants who disagree with the terms or conditions of EPA's approval to submit an objection within 30 days of receipt of registration. In a process analogous to the appeals process for notifications in FIFRA sec. 3(c)(9), EPA would review the applicant's arguments and issue a final decision. EPA would try to review the objection and render a decision within 45 days of receipt by the Agency. It should be kept in mind that EPA's limited resources must be devoted first and foremost to its review period obligations for application decisions; EPA cannot promise that objections to decisions already made will receive equal attention.

9. Determination that the application remains incomplete. EPA may decide that, notwithstanding its preliminary determination of completeness, the application remains incomplete. One reason EPA might determine incompleteness is if the deficiency is the result of the applicant's failure to follow well-established and clearly stated guidance, procedures or policies. Such "incompleteness" could be identified when studies are reviewed in depth and found not to have been conducted in a manner that provides EPA with adequate information on which to reach a decision on the application. This type of incompleteness would normally be discovered only during substantive review. EPA cannot however, preclude the possibility that some deficiencies could be overlooked at the earlier preliminary completeness screening.

EPA expects that it would choose to use the incompleteness determination only rarely after an application is preliminarily determined to be complete, electing instead to deny the application or seek agreement with the applicant on an extension of the review period.

Applications having relatively short review periods ($\leq$ 120 days) are generally straightforward enough that EPA believes it would catch most incomplete applications at the earlier preliminary completeness screening phase. EPA believes there should be few "me-too" type applications that are determined to be incomplete after entering formal review. EPA would rarely seek to extend the original review period for these short-term applications since it is considerably easier in Agency tracking systems to close out a review period altogether than to track an extension. Tracking the review

period is a time-consuming operation. EPA does not believe it should devote its scarce resources to tracking an original review period through a series of short-term extensions. This is especially true given the high volume of applications that fall into the ≤ 120-day review period.

With respect to longer review period applications (>120 days), EPA might choose to determine that an application is incomplete if a deficiency is discovered early in the review process (e.g., in the first 90 days of a 270-day review period).

If, at later points in a lengthy review period (e.g., 200 days into a 270-day review period), EPA judges an application to be deficient for reasons attributable to incompleteness, the Agency would want to examine why this is occurring. Why are incomplete applications being submitted and not being identified earlier in the process? Over time, as process improvements continue to be put in place and EPA and applicants familiarize themselves with new procedures and requirements, EPA expects that incompleteness determinations after beginning Agency review would decrease. Nonetheless, EPA must reserve to itself the right to determine after placing an application into formal review that the application is actually incomplete.

EPA is not obligated to begin review of or compute a review period for an application that is incomplete. If EPA determines after putting the application into formal review and computing a review period that the application is incomplete, EPA would normally stop the review, notify the applicant of its incompleteness, and recompute a new review period upon receipt of submission completing the application. Proposed § 152.455(d)(2)(ii) specifies this typical result.

10. Qualifying Resubmission for Incomplete Applications

However, in its discretion, EPA proposes in § 152.455(d)(2)(i) to offer applicants somewhat more flexibility in Agency review periods if the incompleteness determination occurs after putting the application into formal review and if completing the application can be accomplished on an accelerated basis. For applications having short review periods (≤ 120 days) and minor incompleteness deficiencies, EPA believes that it need not necessarily take the full review period that it would be entitled to when the complete application is resubmitted. Generally, if a minor deficiency can be corrected within 30 days after notice to the applicant, EPA proposes to term that resubmission a "qualifying resubmission" and to complete review within a shorter review period than would otherwise be computed. In general, § 152.455(d)(2)(i) proposes a subsequent review period 30 days shorter than the original base review period for that type of application, i.e., 60 days instead of 90 days for an identical or substantially similar application, and 90 instead of 120 days for an "other new application." The choice to offer an abbreviated review period is entirely within EPA's discretion; EPA could instead take its entire review period.

EPA proposes to limit such "qualifying resubmissions" to applications having a review period of 120 days or less. EPA believes that the incompleteness deficiencies

likely to arise in such applications would generally not be multiple deficiencies and are less likely to involve serious data deficiencies. By contrast, EPA review of an application for a new active ingredient or major new use would in all probability identify multiple deficiencies, including data deficiencies, not amenable to correction within 30 days.

11. Determination that the applicant has not submitted all needed information. If there are deficiencies other than incompleteness deficiencies, the Agency may determine that the applicant has not provided sufficient data or information to make a decision on the application. EPA proposes two procedures (termed Cases 1 and 2); which would apply to any particular application would depend upon the nature of the deficiency. In each case, EPA would stop the review period as of the date that it notifies the applicant of this decision. In neither case would the review period resume until the applicant provided the necessary information, and elapsed time with the applicant would not be counted against EPA's original review period. The difference lies in when EPA would restart the review period (the "clock"). In Case 1, EPA would restart the clock immediately upon receipt of a complete resubmission correcting the deficiencies. In Case 2, EPA would restart the clock only after an additional period after receipt of a complete resubmission.

Case 1. Immediate restarting of the review clock. If the deficiency is one that can be rapidly corrected by the applicant and upon resubmission rapidly reviewed by Agency reviewers without significant Agency downtime to re-review, refamiliarize, or reconstruct the decision logic, EPA would restart the clock as of the date that the applicant resubmitted all information or data required. EPA emphasizes that EPA would restart the clock only after all deficiencies have been corrected. The resubmission must also be "complete." The kinds of deficiencies EPA envisions in this category are short-term studies, upgrading an existing study, or providing an explanation of such studies.

If EPA chose this response, the Agency would specify in its notice to the applicant the deficiencies needing correction, and require that they be corrected within a relatively short timeframe--based upon the type of deficiency, probably less than 6 months. If the resubmission time is too short, the applicant could suggest a longer time for resubmission. If that resubmission time is considerably longer than EPA anticipated, such that the Agency would need additional time upon receipt to refresh its review, EPA would reserve the right to restart the clock at some later time after resubmission (Case 2).

Case 2. Delayed restarting of the review clock. For deficiencies that take longer to correct (e.g., new studies must be generated) or where interruption of EPA review means that EPA must essentially begin some portion of its review again, EPA would restart the clock after both a period for applicant resubmission and an additional time for the Agency to bring the review and reviewer back up to date. The longer the interruption of review, the more likely it is that EPA reviewers may have changed, that policies may have changed or evolved, or that the original reviewer must refresh his

knowledge of the product, the application or the data. In EPA's experience, a review that is interrupted for longer than 6 months has become stale.

In this case, EPA would notify the applicant, specifying the deficiencies and requiring correction by a certain date. EPA would also estimate how long after resubmission the clock would start.

12. Negotiating extended review periods for deficient applications. FIFRA sec.3(h)(3)(F) allows the review period to be extended by agreement between EPA and applicants. As noted earlier, EPA intends that this proposal set boundary rules for extending review periods, so that case-by-case negotiated extensions would be used only infrequently. Deficient applications for which EPA would stop the clock and restart it, but where EPA cannot define the specifics of the resulting extended review period are an area where negotiations would be appropriate. Individual negotiation might be appropriate, for example, if the deficiency entailed development of new methodology or data with which EPA had no prior experience to judge its review time.

Case 1 - Negotiating resubmission dates for simple deficiencies. EPA anticipates it would provide only a limited opportunity for negotiation over the appropriate resubmission time for Case 1 resubmissions. EPA's ability to restart the clock immediately upon resubmission and thereafter to meet the review period deadline depends on the fact that the deficiency can be corrected rapidly. Simply restarting the clock is not feasible if protracted negotiations would result in significant delay in resubmission. EPA's concern is not the effect of the negotiation *per se* on the clock (since the clock will have stopped upon notification of the deficiency), but the fact that any appreciable delay in resubmission because of negotiation may mean that the application review would become stale. EPA must strictly limit the negotiating time for simple deficiencies, or such deficiencies would, because of the passage of time, have to be treated as complex deficiencies under Case 2. EPA does not intend in this rule to define specific types of simple deficiencies for which Case 1 could be used. However, EPA solicits comment on how this procedure could be implemented in a realistic manner, and what would be an appropriate length of time to allow for negotiations to commence and conclude.

Case 2 - Negotiating resubmission dates for complex deficiencies. Resubmission dates would be more flexible with Case 2 complex deficiencies. Because the deficiencies are complex, the resubmission is expected to be on a longer schedule. Since time after notification of a deficiency until resubmission is on the applicant's clock and not EPA's, EPA could be flexible both in negotiating and in the resubmission dates established. Unless the deficiency raised serious risk concerns for a product already on the market (in which case EPA likely would consider denying the application), EPA believes it could generally accommodate applicant timeframes for resubmission.

In addition to interruption of the review period while the applicant corrects deficiencies and resubmits to the Agency, Case 2 negotiations would need to build in

an additional period of time for EPA to "refresh" the application review before the review period clock would start. The appropriate length of this "delay time" is less easily determined and more likely to be an issue that requires negotiation between EPA and applicants. EPA is not proposing either specific delay times or criteria for determining appropriate delay times in this notice, but is proposing to establish the “delay time” as a regulatory decision.

The delay time could be based on several factors. First, the delay time could be a function of the actual time needed for review of the submitted material (which may be one or more new studies). EPA could develop some general timeframes for review of particular types of studies, for example, a standard review time for a chronic toxicology study or an indoor exposure study. These would serve as a starting point for determining the delay time. If EPA develops such standard review times for studies, it would share these with registrants and others before implementing them.

Second, the delay time could also include the time needed for EPA to bring the review and reviewers back up to speed, to adjust for new reviewers, and, once completed, to integrate the new material into the application review and risk assessment. The longer the clock has been stopped and the application put aside, the longer the time needed to refresh it and the more likely that changes in personnel or policies will have occurred. These times are more variable, but may depend in part on the complexity of the application type. The definitions of application types in proposed § 152.445 roughly track the complexity of an original application review and therefore how much re-review might be needed to come up to speed later. EPA expects that the types of deficiencies that would trigger a delay time typically would be associated with new chemicals and major new uses.

Finally, the delay time must of necessity take into account variable external factors such as competing priorities and workload and resource balancing. As a practical matter, although EPA may be able to roughly estimate the delay time when it notifies an applicant of a deficiency, the actual delay time may be dictated not by circumstances at the time of notification, but by circumstances at the time of resubmission. Depending on the nature of the deficiency, and whether new studies must be generated, resubmission could be a year or more away. In that time, substantial changes may have occurred within the Agency that cannot reliably be predicted at the time of notification.

For example, EPA could determine that applications requiring a particular set of tiered data (ecological effects, for example) routinely should require 4 months delay time for a new chemical, taking into account the actual review time and the re-review time. Two years later, when those studies are submitted to the Agency, EPA could be in a situation where its workload has doubled or key personnel are not available, leading to a likely delay time of 6 months.

EPA welcomes comment on how the “delay time” decision process might be structured and administered for maximum efficiency and equity. EPA is considering

how and when negotiations on delay times are most appropriately conducted. EPA solicits comment on criteria, timing and procedures that could be adopted and whether any of these should be regulatory. Realistically, EPA believes that negotiation and agreement on an Agency delay time can take place only at or close to the point of resubmission. Further, EPA believes that negotiation procedures should be informal and non-regulatory to offer the greatest flexibility, and at this time is not proposing regulatory negotiation procedures. EPA seeks comment on the following questions:

* Criteria. What factors are most important in determining how long delay time should be? The type of application? The nature of the deficiency? The elapsed or remaining review period? Other priorities?

*Timing. At what point would discussions between EPA and applicants be most productive and least demanding of time and resources? Soon after notification of deficiencies for planning purposes? Reasonably close to the expected date of resubmission? Only after resubmission and determination that the resubmission is complete?

* Procedure. Should specific negotiation procedures be developed? Are discussions likely to be a frequent occurrence? Should negotiation procedures be developed on a case-by-case, as-needed basis? Are informal procedures sufficient or is there a need for a regulatory framework?

13. Denial for failure to submit required information ("not for cause"). If EPA notifies an applicant of deficiencies, and agrees with the applicant on a resubmission date for the application, and the applicant fails, without good cause, to submit by that date, or fails to submit a "complete" resubmission, EPA has the option of denying the application. A denial of this type (a "not for cause" denial) would not be for reasons of potential adverse effects (a "for cause" denial), but because the applicant has failed to submit the information the Agency required to reach a decision on the application.

Several readings of FIFRA sec. 3(h)(3)(F)(I) are possible with respect to a denial action the Agency may take as the endpoint of a review period. EPA believes some interpretations, while plausible and logical, would not likely achieve what we believe the Congress intended. EPA is instead adopting an interpretation that we believe both advances the goal of Congress that the Agency institute reforms to improve the antimicrobial decision making process, and preserves the rights of applicants under the statutory framework for denials under FIFRA sec. 3(c)(6).

Under one possible reading of the statute, the Agency would review the application under the review periods specified in § 152.457, and within those same review periods take all the actions required under FIFRA sec. 3(c)(6) for denials, including a 30-day notice of intent to deny prior to actual denial. This interpretation would effectively shorten the review periods established by section 3(h) by 30 days, a

result that would be particularly acute in the case of short review periods such as those of 120 days or less. In establishing the review periods, Congress considered the amounts of time the Agency requires to review various types of applications. Each review period goal was intended to provide a streamlined yet presumably adequate amount of time for the Agency to review these applications. The Congress realized that in some instances these times would not be adequate and allowed for the Agency and applicant to extend the applicable review period through mutual agreement. We do not believe that Congress would on the one hand acknowledge EPA's possible need to extend review periods, while at the same time effectively diminishing each review period to accommodate the correction period for FIFRA sec. 3(c)(6) denials.

An equally plausible interpretation is that FIFRA sec. 3(h)(3)(F)(i) overrides the provisions of section 3(c)(6) altogether. Under this interpretation EPA would not have to issue a 30-day notice of intent or provide opportunity for a hearing. However, there is no indication of Congressional intent to diminish the opportunity for an applicant to remedy deficiencies and/or request a hearing for denials of applications.

EPA believes a third interpretation is reasonable and more appropriate. EPA would regard the Notice of Intent to Deny (NOID) required by FIFRA sec. 3(c)(6) as the practical equivalent of a denial under FIFRA sec. 3(h). At the point a decision is reached under § 152.457 (including any extended review periods), EPA would commence the FIFRA sec. 3(c)(6) denial process by issuing a NOID. Under this interpretation, the Agency would have the full review period contemplated by Congress, and applicants would be afforded the protections intended for FIFRA sec. 3(c)(6) denials. Accordingly, § 152.455 would provide that the 30-day NOID itself constitutes the denial decision required by section 3(h)(3).

Denial under FIFRA sec. 3(h)(3) would be the same as denial under FIFRA sec. 3(c)(6). Legally, EPA would find that the applicant has failed to meet the registration standard of section 3(c)(5), in that "its labeling and other material required to be submitted" do not "comply with the requirements of the Act." EPA's determination to deny an application would set in motion a process that entails the NOID, opportunity for the applicant to correct the application deficiencies within 30 days, final denial if deficiencies are not corrected, and the opportunity for an administrative hearing process. Denial procedures are found in § 152.118.

EPA would be unlikely to allow additional time for correction beyond the 30 days provided by the NOID, for several reasons. First, EPA has already notified the applicant previously and agreed upon an appropriate time for submitting additional data (of a long-term nature). Additional discussion at this point would not seem justified in light of the previous negotiations. Second, as noted earlier, EPA's tracking system will be strained if EPA must repeatedly recompute the elapsed review period due to extensions, new resubmission dates, or additional EPA review times. EPA and applicants will not be well served if tracking system needs overwhelm the review process. At some point, EPA must reach closure on an application. Finally, there is the issue of equity among applicants. Negotiating time for *any* application is decreased

review time for *all* applications, and should be allocated evenly across applications rather than consumed on a single undeserving application.

As an alternative, EPA could determine that the failure to resubmit properly and on time renders the application incomplete. In either case, the effect on the review clock is the same: it would start over whenever the applicant submitted the complete data or properly completed the application.

14. Denial for failure to meet the registration standard ("for cause"). Finally, as already provided by the statute, EPA can determine that an application should be denied because the pesticide or its uses pose unreasonable adverse effects on man or the environment (a "for cause" denial). Legally, EPA would determine that it fails to meet the registration standard of FIFRA sec. 3(c)(5)(C) or (D).

As in the case of a not-for-cause denial, EPA would follow the denial procedures of FIFRA sec. 3(c)(6) and § 152.118. Also as above, EPA would treat the NOID as the decision required by FIFRA sec. 3(h). EPA expects a denial for cause to be a rare occurrence.

H. Review Periods

1. Statutory provisions. Although FIFRA sec. 3(h) is premised upon the establishment of decision-making deadlines, it does not prescribe a specific set of review periods that EPA must adopt by regulation, However, section 3(h) does contain two sets of review periods that express Congressional intent in this area. EPA has given careful consideration to each, discussed in this unit, and is today proposing one.

First, section 3(h)(2) establishes review time period reduction "goals," ranging from 90 days to 540 days, whose achievement is tied to the implementation of the process reforms required by section 3(h)(1). Under section 3(h)(1), the explicit purpose of the process reforms is to achieve the "goal" review periods. The statute stops short of requiring that EPA adopt by regulation a set of statutorily-mandated review periods. The statute appears to anticipate that EPA's management reforms might take some time to fully implement to achieve the goal review periods: section 3(h)(4) requires EPA to submit an annual report to appropriate Congressional committees documenting its progress toward the goals. Thus, while EPA is to work toward the goal review periods, Congress did not require EPA to adopt the "goal" review periods in its regulation. EPA may include other review periods in the regulation so long as it complies with other requirements triggered if the goals are not met.

Congress did, however, intend that EPA should take the goal review periods seriously, and therefore put in place two provisions that are triggered if EPA does not meet the goal review periods. The annual report mentioned above is to be submitted "beginning on the date of enactment of this subsection and ending on the date that the goals under paragraph (2) [the goal review periods] are achieved." Thus, as long as EPA is not meeting any statutory "goal" review periods, for whatever reason, it must

continue to report to Congress on its progress. The first such annual report was issued in October 1997 (EPA 739-R-97-001).

Moreover, if EPA issues a final regulation that fails to meet any of the goals, it also must comply with the requirements of section 3(h)(3)(B)(ii) by identifying in the final rule any unmet goal, explaining why the goal was not met, describing the elements of the regulations included instead, and identifying future steps to attain the goal. Again, the statute does not require that EPA propose a statutorily-identified set of regulatory review periods, though a timeframe is required to be included in the regulation.

The second statement of Congressional intent, in section 3(h)(3)(D), establishes "default" review periods, ranging from 90 days to 2 years, that automatically took effect on April 25, 1998, since EPA's final regulation was not effective by that date. The "default" review periods are equal to or longer than the "goal" review periods, depending upon the type of application. After promulgation of this regulation, the default review periods will be replaced by review periods specified in the final rule. In the legislative history of the antimicrobial provisions, it is stated that "maximum time periods for review are specified in Subtitle B for various activities." [Subtitle B contains the amendments in FIFRA sec. 3(h)]. Since the default review periods are in fact the "maximum review periods specified" in section 3(h), this language could be read to suggest that Congress intended the default review periods to be adopted by the Agency in its regulation. However, EPA views the "default" review periods as a "hammer" provision to encourage timely promulgation of its antimicrobial final rule containing EPA-specified review periods, rather than a statement of Congressional intent as to what review periods should be adopted.

2. EPA proposal. EPA is today proposing the "goal" review periods. Since these are the benchmark of the management and process reforms contemplated by Congress, EPA believes they are more appropriate than any other review periods, which would of necessity serve only in an interim capacity until the "goal" review periods could be met. As an alternative, EPA could consider and would like comment on the options of: adopting no review periods by regulation and relying on administrative review periods; adopting the "default" review periods; or adopting some other review periods. Commenters who support this last option should be specific as to the review periods sought and why. If other than the goal review periods are ultimately adopted, EPA would strive to meet the goal review periods, as it has since FQPA was enacted.

Section 152.457 of today's proposal sets out EPA's proposed review periods. The three tables in that section address, respectively, approvals of new registrations, amended registrations, and "qualifying resubmissions." As noted in Unit VIII.D., EPA proposes to review an application for a major new use within 270 days, regardless of whether that application is a new registration or an amendment to an existing registration. Accordingly the tables in § 152.457(c) and (d) both include “major new use.” Proposed § 152.457 also sets out the limitations of applicability of review periods.

3. Food use antimicrobial products. As defined by FIFRA sec. 2(mm),

antimicrobial pesticides do not include products whose intended use would require a clearance under the FFDCA. As noted in Unit VI.B., EPA intends to apply this exception so as to exclude only applications that would require a new or revised clearance. Applications subject to an existing clearance (that does not need revision) would be antimicrobial pesticides.

4. Wood preservatives. The statutory definition also excludes aquatic herbicides and some wood preservatives and antifoulants from definition as "antimicrobial pesticides." Applications for registration of such products are not covered by subpart W and are not eligible for the review periods of § 152.457.

However, under FIFRA sec. 3(h)(3)(E), applications for wood preservatives (and *only* wood preservatives) *are* eligible for the statutorily-required review periods that would be established by this proposal if they meet certain conditions:

*First, the application must be for a wood preservative that bears an antimicrobial claim as defined in FIFRA sec. 2(mm), even if other non-antimicrobial wood preservative claims (such as fungus or insect protection) are made.

*Second, the data requirements to support the wood preservative product that is not an "antimicrobial pesticide" must be the same as the data requirements that support a wood preservative that is an "antimicrobial pesticide." In general, the data requirements in part 158 are the same for all wood preservatives, regardless of the type of wood preservative claim made. Thus, all wood preservative products fulfill this criterion.

*Finally, the applicability of the statutorily-required review period to a wood preservative application is to be "consistent with the degree of risk posed by the use of the wood preservative." EPA interprets this clause to permit the Agency, in its discretion and on a case-by-case basis, to determine that an individual wood preservative application is not subject to the statutorily-required review period based on risk concerns.

For example, EPA might exercise this discretion for an application that initially would have a review period of 180 days. During the review, however, EPA discovers that the wood preservative use poses significantly greater risks than a typical "substantive new use" application. This might occur if the treated wood were intended for use in a manner that greatly increased or changed the exposure potential to humans or other species. To evaluate the increased risk, EPA might need more than 180 days, even if substantial new data were not required. In this situation, EPA would notify the wood preservative applicant that the application was no longer entitled to a statutorily-required review period, and specify the risk reasons therefor.

EPA would make every effort in its notification to estimate when the application review would be completed, although the application would no longer qualify for review period coverage. EPA regards its notification to the wood preservative applicant of a

risk differential basis for review as relieving EPA of its obligation to complete review within any statutorily-required review period.

5. Fast-track applications. Fast-track applications are described in FIFRA sec. 3(c)(3). Fast-track applications are not limited to antimicrobial products, and EPA is required to reach a decision on the application within 90 days. Currently, there are no regulations for fast-track applications, and none are needed because the statute sets out clear deadlines for completion of review. The review period for an antimicrobial pesticide specifically does not affect or substitute for the timeframe for a fast-track review of an antimicrobial pesticide. Generally, antimicrobial applications for identical or substantially similar new products or minor amendments are equivalent to fast-track applications, and would be decided under either provision within 90 days.

As a legal matter, however, an application must be reviewed either as a fast-track application or an antimicrobial application--a single application cannot be both. EPA interprets FIFRA sec. 3(h)(3)(F)(iii) to place an application that could qualify as either a “fast-track” or “antimicrobial pesticide” application squarely under the antimicrobial provisions and review periods. While there are minor procedural differences between 90-day fast-track decisions and 90-day antimicrobial review period decisions, the significant difference between the two is that a fast-track action is not judicially reviewable if EPA fails to render its decision within 90 days while an antimicrobial action is judicially reviewable.

X. Duration of Registration for Products Bearing Public Health Claims

EPA proposes in § 152.458 to establish terms for a time-limited registration of products bearing a public health claim. The term of a registration would be limited to no more than 5 years. The registration could be continued only if the registrant conducts product analysis and efficacy testing that confirms that the product continues to meet the applicable registration standards of FIFRA sec. 3(c)(5). EPA believes that it is authorized to establish this provision under the authority of sections 3(h) and 25(a).

A. Statutory Requirements

FIFRA sec. 3(h)(3)(A)(ii)(IV) mandates two things: 1) that EPA " . . .ensure that the registration process is sufficient to maintain antimicrobial pesticide efficacy”; and 2) that “antimicrobial pesticide products continue to meet product performance standards and effectiveness levels for each type of label claim made." Section 3(h) focuses on the registration process as a means of ensuring continued product performance. More important, however, is the strong Congressional directive to ensure continued product performance and effectiveness after registration. Thus, under section 3(h), EPA must address post-registration efficacy in the antimicrobial regulation proposed today.

EPA is also authorized under FIFRA sec. 25(a) to issue regulations to carry out the provisions of the Act. Such regulations must specifically "take into account the

difference in concept and usage between various classes of pesticides, *including public health pesticides* and differences in environmental risk and the appropriate data for evaluating such risk between agricultural, nonagricultural, *and public health pesticides*." " Public health pesticide" is defined in FIFRA sec. 2(nn) to include, among other things, pesticide products intended for use against "viruses, bacteria, or other microorganisms . . . that pose a threat to public health." The references in FIFRA sec. 25(a) singling out public health pesticides were added by FQPA, and EPA regards their addition as expressing Congressional intent that public health pesticides as a class should be distinguished from other pesticides when considering regulatory requirements, including this proposal.

Taken together, EPA believes that the clear Congressional intent expressed in section 3(h) to ensure post-registration product performance and effectiveness, coupled with the authority conferred by section 25(a), authorize EPA to establish by regulation binding requirements on registrants of antimicrobial public health products to ensure continued product efficacy. The requirements relate to initial registration and also extend into post-registration activities.

B. Alternatives Considered

As noted in Unit IV.E., EPA has relied on enforcement mechanisms to ensure post-registration efficacy; EPA will continue to use these as appropriate. But, because failure of an antimicrobial public health product to work as intended cannot normally be detected by the user and can have serious health and safety consequences or other unreasonable adverse effects, it is critical that EPA use all available regulatory and enforcement mechanisms to ensure public health protection.

One means of ensuring continued efficacy after registration would be through the statutorily required re-review of products. FIFRA contains two provisions that require EPA to reassess each registration according to the latest scientific standards, which for public health products would include an efficacy review. FIFRA sec. 4 requires a one-time reregistration of each product first registered before November 1984. This process is underway, but to date few antimicrobial products have been reviewed under section 4, and products registered since 1984 are not subject to reregistration. Additionally FIFRA sec. 3(g) requires EPA to periodically review each registration, with a goal of re-reviewing each product every 15 years.

Although these provisions will be useful in ensuring that pesticide products continue to meet the registration standard, based upon up-to-date scientific standards, EPA believes that more product oversight is needed to meet the mandate of FIFRA sec. 3(h) to ensure continued efficacy of antimicrobial public health products. Neither a one-time re-review nor a periodic review only every 15 years offers adequate assurance of continued efficacy of products so critical to public health protection. EPA believes that by requiring the re-testing of products at more frequent intervals than every 15 years, complemented by EPA, State and other testing programs, it can be better assured of continued product efficacy, without incurring to itself or imposing upon

registrants significant additional costs.

Alternatively, EPA could establish, or require registrants to establish, an ongoing quality control and efficacy monitoring program to evaluate product composition and efficacy on a frequent basis. EPA conducted a one-time testing of sterilant products, and is conducting similar testing of hospital disinfectant products. EPA believes that many antimicrobial registrants, fully aware of the need for continuing quality control and efficacy, already test their products on a routine basis, although EPA currently has no data on the number of producers who do so, the type of testing conducted, or how frequently it is done. A formalized testing program, whether by EPA or registrants, would obviously be one way to meet the mandate of FIFRA sec. 3(h), and, if conducted at frequent intervals, would offer the greatest assurance of continued product performance and public health protection. EPA itself does not have the resources to establish and sustain such a program, and so EPA proposes that registrants bear the cost of such testing. Two approaches have been considered, and one is being proposed today.

One such method would be to require that a public health applicant develop and submit for Agency approval as part of his application for registration or reregistration a plan for continuous quality control and efficacy testing. Such a requirement would meet the mandate of using the registration process to ensure efficacy, as well as ensuring continued post-registration needs. Upon approval of the registration or reregistration, the plan would become a term of the registration and would be binding on the registrant. The benefit of this approach is that public health applicants would be afforded the greatest flexibility to design a program that they believe satisfies the needs of the Agency. However, approval of a plan would require greater review resources for the Agency, and potentially lead to delays in approval beyond the established review periods required by § 152.458. Comments are requested as to the value, feasibility, and potential costs of such a requirement, as well as criteria for evaluating plans. EPA is not proposing this option today, but could adopt it in the final rule. If EPA does so, it would include the requirement for a public health quality control and efficacy monitoring plan in § 152.450.

EPA seeks information on current registrant- or producer-imposed quality control measures, whether producers are currently routinely conducting efficacy testing on a batch basis or at frequent intervals, and what type of testing is conducted. Finally, comments are solicited on any additional ways of ensuring continued efficacy of public health products; suggestions would be considered for future implementation, either administratively or by regulation.

C. Sunset Provision

1. Maximum 5-year registration term. EPA proposes to implement a periodic and regular testing program by limiting the duration of a new antimicrobial public health registration to no more than 5 years from the date of initial registration of the new product. EPA would incorporate the 5-year expiration into the approval of the

application as a term of registration. Every 5 years, in order to avoid expiration, the registrant would have to conduct the testing described in § 152.458(b)(3) and certify that the product has passed the tests.

The Agency is also proposing to require testing every five years as a prerequisite for maintaining the registrations of existing products, i.e., products registered as of the effective date of this rule. For existing products, the 5-year period would begin on the earliest of: (1) the date of first amendment after the effective date; (2) the date of reregistration under FIFRA sec. 4; or (3) a date certain approximately six months after the effective date of the rule. EPA would in the final rule specify the date certain, which, based on current projected schedules, would be no earlier than August 1, 2000. This last date would ensure that all products registered at the time this rule becomes effective would be brought into the retesting scheme.
EPA expects that this default date would govern for most existing products, since the number of amendments and reregistrations that could be expected in the six-month period is unlikely to approach the number of public health registrations (currently estimated at approximately 3000 products).

In the case of an amendment or reregistration, EPA approval letters would include the 5-year requirement. Because there would otherwise be no Agency notification for products that become subject on the specific default date, EPA would notify all such registrants of the effective date.

EPA is proposing this phased introduction of the testing requirement for existing products because it believes that phased testing will create less strain upon laboratory demand for testing and upon Agency resources. It would, however, complicate the tracking of expiration dates.

As an alternative, EPA could begin the 5-year retesting requirement on a single date for all existing products. While this would ensure equity for existing products and simplify calculation of expiration dates for both registrants and the Agency, it could lead to high demand for laboratory testing on a compressed schedule every 5 years. Even with a single date for existing products, new products would become subject to the retesting requirement on a phased basis as they are registered; thus, there would always be some phasing of the retesting requirement. Over time, as new products are registered and existing ones taken off the market, the phased testing scheme would become the norm rather than the exception. If EPA were to adopt a single date, it would specify the date in the final rule.

In any case, the scope of EPA's determination of continued registrability at the 5-year intervals would be limited to the composition and efficacy standards in FIFRA sec. 3(c)(5)(A) and (C), i.e., that the product's composition "is such as to warrant the proposed claims for it," and that "it will perform its intended function [without unreasonable adverse effects on the environment]." EPA's evaluation would be limited to products bearing public health claims and its determination to whether the product would perform its intended function at the antimicrobial levels claimed. EPA would not

expect to reevaluate the potential adverse effects of the product every 5 years, but generally would reserve such evaluation for a 15-year review cycle. Thus, in any given 15-year period, EPA typically would review each product once under the 15-year statutory review provision and 3 times for efficacy purposes. Notwithstanding these scheduled review intervals, EPA may conduct a review of a product for any purpose (including, but not limited to, efficacy concerns) at any time and take regulatory or enforcement action based upon its findings.

EPA believes that a quality control check and efficacy evaluation at least every 5 years is needed to ensure continued efficacy. However, the Agency solicits comment as to whether a different registration term should be implemented, either more or less than 5 years.

2. Data requirements. To meet the product composition standard, proposed § 152.458 would require a chemical analysis demonstrating that the product conforms to the composition approved by EPA on the most recent Statement of Formula, conducted according to the analytical method that the registrant is required to provide the Agency under 40 CFR 158.180.

To meet the product efficacy standard, proposed § 152.458 would require that the registrant conduct the battery of efficacy tests that would be required to support the product if it were submitted for new registration at that time, conducted in accordance with the most current Agency testing guidelines. Testing guidelines for antimicrobial products are evolving, and testing would have to reflect the methods and standards recognized by EPA at the time of the required testing.

To ensure that the testing reflected the product as distributed and sold at the 5-year mark, the testing would have to be conducted during the final year of the 5-year registration period (or other renewal period if 5 years is not selected). Although EPA believes it is in the interest of registrants to conduct such analysis and testing more frequently as a matter of good business practice, only testing conducted within the last year could be used to support renewal of product registration.

3. Certification procedure for compliance. EPA believes that it can accomplish this limited renewal program and monitor compliance without routinely reviewing the actual test results. In accordance with the mandate of FIFRA sec. 3(h)(3)(B)(iii) to "consider the establishment of a certification process for regulatory actions involving risks that can be responsibly managed . . . in the most cost-efficient manner," EPA proposes to use a certification process as the most cost-effective means of administering the program. Each registrant would certify in writing to the Agency that the testing had been conducted as required in accordance with EPA Good Laboratory Practice standards, and that the results demonstrate that the product meets the composition and efficacy standards specified. The certification must be signed by an authorized representative of the registrant. As a condition of registration, EPA would require that test results be made available immediately to EPA upon request; EPA expects that it would selectively review the data for some products.

The required certification would have to be submitted to the Office of Pesticide Programs no later than 90 days prior to each successive expiration date of the registration, to allow sufficient time for EPA to process it and notify the registrant of its determination. If at any time after the renewal, the Agency determined that the certification was false or the data upon which it was based do not support the certification for any reason, the registration would be subject to regulatory or enforcement action or both.

4. Failure to submit. EPA would not notify registrants of the upcoming expiration of their product registrations. Registrants would be responsible for monitoring the status of their registrations, conducting the testing and submitting the required certification in a timely manner. Failure to submit would result in the expiration of the registration automatically and without hearing rights. If the registration expired, the registrant would have to submit a new application for registration to once again market the product.

If EPA has no other information or data to suggest that the product is no longer efficacious, EPA would permit the registrant 90 days to distribute and sell his existing stocks of product (product in existence on or before the date of registration expiration). Product already distributed by the registrant and in channels of trade could be distributed and sold for one year after expiration.

5. Products that fail efficacy testing. If a product fails efficacy testing at its 5-year renewal, the registrant would be unable to certify as required by § 152.458, and the product registration would expire at its 5-year anniversary.

Moreover, there is a continuing obligation under FIFRA sec. 6(a)(2) to report information concerning adverse effects to the Agency, and that in certain cases this obligation extends beyond the life of the registration (for example, to an expired registration). If the registrant conducts efficacy testing at any time, and the product fails to meet the performance standard of part 156, subpart W, for each public health claim, the registrant is required to report such failure to EPA in accordance with the procedures and timeframes in 40 CFR part 159. Section 159.188 of that chapter specifically details the information required to be submitted concerning antimicrobial public health products. The requirement to submit under FIFRA sec. 6(a)(2) and the regulations in 40 CFR part 159 is a separate requirement from that under the this proposal.

X. General Conditions of Registration

EPA proposes in § 152.459 to establish conditions of registration for antimicrobial pesticides. Under FIFRA sec. 3(c)(7), EPA is authorized to register pesticide products conditionally. Current regulations in § 152.115 implement EPA's authority, and specify general conditions applicable to registrations. Section 152.115(c) permits EPA to establish, on a case-by-case basis, other conditions applicable to

registration under FIFRA sec. 3(c)(7).

For antimicrobial pesticides, EPA proposes in § 152.459(a) to cross-reference the conditions of § 152.115. These conditions relate primarily to submission of missing data subsequent to registration.

Further, EPA proposes to establish as a condition of registration a requirement that registrants of non-public health products submit efficacy data upon request by the Agency. Registrants are currently required to maintain efficacy data for non-public health products, but EPA does not routinely review them as part of the application. Upon request, registrants are required to submit the data. When this request is made prior to approval of a new application, EPA can refuse to register the product if the registrant does not comply. EPA proposes in § 152.459(b) to establish as a condition of registration that registrants must submit upon request any efficacy data for a non-public health product that were not required to be submitted with the application. By establishing submission as a condition of registration, EPA makes explicit the authority and action it will take (expedited cancellation under FIFRA sec. 6(e)) if registrants fail to provide these data after registration.

XI. EPA/FDA Jurisdiction over Antimicrobial Products Used in or on Food

A. Background

Since EPA was created in 1970, EPA and FDA have shared authority under FFDCA over pesticide residues in food. Prior to FQPA, the division of jurisdiction between EPA and FDA was governed by a number of somewhat complicated provisions of FFDCA. FQPA modified the FFDCA to create much clearer lines of jurisdiction. In the process, FQPA transferred to EPA regulatory responsibility for a number of antimicrobial substances which for many years had been under FDA jurisdiction.

In the two years after FQPA enactment, EPA and FDA held extensive discussions on their respective legal authorities pre- and post-FQPA. The two agencies issued in the Federal Register on October 9, 1998 (63 FR 54532) a joint *Federal Register* notice entitled "Legal and Policy Interpretation of the Jurisdiction under the Federal Food, Drug and Cosmetic Act of the Food and Drug Administration and the Environmental Protection Agency over the use of Antimicrobial Substances with the Potential to Become Components of Food" [hereafter "Policy Interpretation"]. In that notice EPA and FDA discussed a proposed allocation of jurisdiction over antimicrobial substances which would transfer back to FDA regulatory authority over many of the substances that had been transferred to EPA in 1996 by FQPA.

EPA would have effected the transfer in a subsequent regulation by revising its declaration of a FIFRA "pest" in § 152.5 to exclude certain microorganisms occurring in food processing facilities, packaging and food contact articles. Readers are referred to the Policy Interpretation for a full discussion of the proposed approach.

B. FDA Regains FFDCA Jurisdiction

On October 30, 1998, however, Congress passed the ”Antimicrobial Regulation Technical Corrections Act of 1998” (ARTCA), P.L. 105-324, which amended FFDCA sec. 201(q)(1) and 408(j) in a manner that essentially accomplished the two Agencies’ planned regulatory approach, and obviated the need for EPA to issue regulations. ARTCA supersedes the Policy Interpretation with respect to FFDCA regulatory authority over antimicrobial residues in food, except for residues of ethylene and propylene oxides, which were retained as “pesticides.” ARTCA, however, does not address the interpretation of the FIFRA term ”processed food” that was included in the Policy Interpretation.

C. EPA Retains FIFRA Jurisdiction

Under the Policy Interpretation, EPA intended to propose to yield both FFDCA and FIFRA authority over those antimicrobial substances addressed in the Policy Interpretation. EPA and FDA viewed the regulatory approach of redefining FIFRA

”pests” to be the best means of accomplishing the transfer agreed upon between the Agencies. No authority under FFDCA would have achieved this objective before passage of ARTCA.

Unlike the proposed change discussed in the Policy Interpretation, however, the statutory change put in place by ARTCA affects only FFDCA authority over antimicrobial residues in food. ARTCA does not affect the status of any substance as a ”pesticide” within the meaning of FIFRA. The legislative history of ARTCA makes this point clear:

> [This amendment would affect the regulation of antimicrobial pesticides only under the FFDCA. EPA would continue to regulate antimicrobial pesticides under FIFRA, and EPA’s authorities under that statute would not be changed.

In light of ARTCA, which provides specific Congressional direction, EPA is not proposing to exclude or exempt these products from FIFRA requirements, as discussed in the Policy Interpretation.

Because the legislation is complex, EPA has developed an overview table of current FFDCA authority post-ARTCA. Table 4 below is an overview of antimicrobial substances whose use may result in residues in food. Column 1 lists the category of antimicrobial substances. Column 2 further subdivides the major categories. Column 3 gives the current jurisdiction under FFDCA over antimicrobial substances after ARTCA. Note that, even where FFDCA authority is vested in FDA, EPA retains FIFRA authority for antimicrobial products other than those used on processed food. Such products will continue to require registration.

TABLE 4--JURISDICTION UNDER FFDCA OVER RESIDUES OF ANTIMICROBIAL SUBSTANCES IN OR ON FOOD[a]

Use sites/categories	Subcategories, if applicable	Current Jurisdiction under FFDCA
1. Edible raw agricultural commodities	a. Pre- and post-harvest field use on crops	EPA
	b. In a food processing facility[b]	FDA
	c. Consumer use (e.g., home gardens)	EPA
2. Process water that contacts edible food	a. Post-harvest treatment[c] of raw agricultural commodities	EPA
	b. In a food processing facility[b]	FDA
	c. Consumer use (e.g., home produce washes for raw agricultural commodities)	EPA
3. Edible processed food	All uses	FDA
4. Animal drinking water	Uses other than animal drugs	EPA
5. Permanent or semi-permanent food-contact surfaces	All sites, including food processing facilities[b]	EPA
6. Production of food packaging materials and in or on finished materials, including plastic, paper, and paperboard	All, regardless of whether the food to be packaged is a raw or processed food	FDA
7. Production of food-contact articles, other than food packaging	a. No intended antimicrobial effect in the finished article; any ongoing effect is not an effect on the surface of the article	FDA

	b. An intended ongoing antimicrobial effect on the surface of the finished article	EPA

[a]The term “food” is defined according to FFDCA sec. 201(f).

[b]EPA has used this term for convenience in this overview table. FFDCA sec. 2(q)(1)(B) describes the scope of activities to include ”locations where food is prepared, packed or held for commercial purposes.”

[c]EPA has used this term for convenience in this overview table. FFDCA sec. 2(q)(1)(B) describes the scope of these treatments to include (1) treatments in facilities where the treatment does not change the raw agricultural status of the food; and (2) treatments applied during transportation between the field and the treatment facility.

XII. Efficacy Performance and Labeling Standards for Antimicrobial Products

EPA proposes to create a new Subpart W (§§ 156.440 through 156.458) in part 156, entitled *Public Health Claims for Antimicrobial Pesticides.* Subpart W would establish labeling requirements for antimicrobial pesticides that make public health claims based upon the level and type of efficacy demonstrated by testing. The efficacy performance standards upon which the proposed requirements are based are derived from the testing requirements of 40 CFR part 158, and the test methods and standards provided in Subdivision G of the Pesticide Assessment Guidelines. Today's proposal would also codify certain labeling requirements that are currently applied to antimicrobial pesticides individually at the time of registration, but are contained only in Guidelines (Subdivision H of the Pesticide Guidelines). Neither the performance standards nor the labeling requirements are a departure from current and longstanding policies.

A. Need for Rule

EPA bears a special responsibility to ensure that antimicrobial efficacy for public health products be substantiated and maintained over the life of the product because of the potentially serious consequences of lack of efficacy, and the fact that users cannot independently ascertain product efficacy. For that reason, EPA not only must review antimicrobial efficacy data to ensure that products indeed perform at the claimed level of antimicrobial activity, but also must assure that product labeling accurately expresses the type and level of activity to be expected. Effective control of public health pests is not only a function of the availability of products that work as intended, but also of users' ability to select an appropriate product for their needs, and to use it properly. The product labeling is critical in conveying this information. By issuing performance standards and associated labeling standards as rules rather than the current Guidelines, EPA expects to ensure consistency in labeling, promote a common understanding among registrants and the user community of performance expectations and limitations, and thereby maintain the benefits of these products in protecting public health.

B. 1984 Proposal

EPA originally proposed these performance and labeling standards in substantially similar form in 1984 as part of a larger general pesticide labeling proposal (September 26, 1984, 49 FR 37959), but did not finalize them. Because of the intervening time, EPA is reproposing those efficacy performance and labeling standards today. In response to the 1984 proposal, EPA received 8 comments pertaining to the efficacy performance and labeling standards. The commenters included two trade associations (the Chemical Specialties Manufacturers' Association and the International Sanitary Supply Association), and 6 individual producers of antimicrobial pesticides. A copy of these comments or a summary is available in the public docket. EPA has not reviewed these comments in detail for this new proposal, and invites commenters to reiterate any comments they believe are relevant to this proposal.

C. Current Proposal

Every pesticide product must be properly labeled, in accordance with general labeling requirements of part 156, including, among other things, use directions that describe the site of application, the target pests associated with each site, the dosage rate, the method of application, the frequency and timing of application and any particular limitations on use. Antimicrobial products covered by subpart W must comply with part 156 labeling requirements. In addition, for public health antimicrobial products, the labeling must identify the type and level of antimicrobial activity demonstrated by efficacy testing. A product that does not meet the applicable performance standard of proposed Subpart W for a specified level of activity (such as sterilizer, disinfectant, or sanitizer) or type of activity (tuberculocidal, virucidal) may not be identified as such on the label, and, in some cases, will be required to bear a disclaimer to make clear the limitations of product performance.

Under proposed § 156.440, the applicability of subpart W to antimicrobial products is the same as that in part 152, subpart W. This will ensure that all antimicrobial public health products, not just those meeting the definition of " antimicrobial pesticide," are subject to the efficacy performance and labeling standards. This clarifies the status of food use antimicrobials, which are excluded from the statutory definition, but covered under EPA's proposed rule.

Moreover, proposed § 156.440 would limit applicability of subpart W to end use products. EPA does not expect manufacturing use products to make specific public health claims. Typically a manufacturing use product must be supported by basic presumptive efficacy testing demonstrating that the active ingredients are capable of antimicrobial activity. The labeling typically bears information on the results of these screening or presumptive efficacy tests. End use products must, however, be supported by specific efficacy data on the end use formulation, on the sites and under the expected conditions of use of the product itself. The performance standards on which the labeling standards of subpart W rely are based upon end use product testing, not presumptive testing of manufacturing use products. The labeling statements and limitations therefore would also relate only to end use products.

Proposed § 156.441 contains pertinent definitions, including the levels of antimicrobial activity that are permitted on labeling (e.g., sterilizer, disinfectant, sanitizer). This listing is not necessarily exhaustive; in the future, EPA may define additional categories of antimicrobial activity or public health pesticides.

Proposed § 156.443 describes what types of claims EPA considers to be public health claims. In general, public health claims encompass three types of claims: (1) claims of control of specific microorganisms that are pathogenic to man; (2) claims of levels of antimicrobial activity that are associated with public health protection (e.g., disinfect), even if specific organisms are not named; and (3) claims that make non-specific assertions relating to impact on public health or safety, e.g., "provides a

germ-free environment." The use of such terms on a product label is deemed to bring a product within the ambit of FIFRA regulation as a public health product.

Among the last, EPA has specifically included reference to the term "sanitary" as an antimicrobial public health claim. EPA believes that this is a logical extension of the term "sanitize," that should be considered to bring a product under FIFRA regulation as a public health pesticide. EPA regards a product that claims to “create a sanitary environment” or is intended to achieve “sanitary” effects beyond itself to be making an assertion of impact on public health. The presence of such a claim would clearly constitute a pesticide claim.

At the same time, EPA recognizes that the term “sanitary” may be used on a product in the more traditional sense of “hygienic,” i.e., to convey the fact that the product is clean or has been treated to render it free of harmful organisms (for example, “ sanitary” napkins). When used in such a sense, EPA believes that there is no intent or claim that the product will have an antimicrobial function beyond protection of itself. In the absence of an express claim, EPA proposes to consider the claim “sanitary” as an implied pesticide public health claim, and the product on which it appears as a pesticide subject to FIFRA, if: (1) the product composition is similar to other products registered under FIFRA that make antimicrobial claims; or (2) the product contains a substance that is capable of antimicrobial activity at the levels in the product and there is no other functional reason for the ingredient to be present in the product. The burden would be on the producer of a product that makes a “sanitary” claim to demonstrate that the claim is not a public health claim. EPA seeks comment as to whether its interpretation of "sanitary" claims is sufficiently clear to unambiguously delineate pesticide products or whether it could be overly broad and draw inappropriate products under FIFRA.

Proposed § 156.444 lists examples of specific antimicrobial-related claims that EPA considers to be unacceptable because they are misleading. These are an extension and clarification of existing prohibitions against false and misleading statements found in § 156.10(a)(5). Again, the listings are intended to be exemplary; EPA may determine on a case-by-case basis that a label statement or claim is misleading.

A product that bears a public health claim, but which does not meet the performance standard for that claim in subpart W would be considered misbranded under FIFRA sec. 12(a)(1)(E). Registrants have been on notice of the unacceptability of these statements from previous and current Agency guidelines and policies. On the effective date of the final rule, EPA would prohibit these claims from appearing on new products. To ensure that all registrants of current products are provided adequate notice and have ample opportunity to evaluate their label statements and delete or modify those that are unacceptable, EPA proposes to permit registrants a 6-month period in which to modify labeling before the Agency would find the products to be misbranded. As of a date approximately six months after the effective date of this rule,

the actual date to be specified in the final rule, EPA may take action against any product that it determines is misbranded based upon the criteria in proposed § 156.444. EPA requests comments on whether a 6-month period for label compliance is adequate. Based on comments, EPA may in the final rule adopt a compliance date of more or less than 6 months.

The remainder of subpart W (§§ 156.445 through 156.458) describes the performance standards and acceptable claims that may be made for various antimicrobial public health pesticides. Each section generally contains the following:

1. The performance standard for a level of antimicrobial efficacy on a specified site, (e.g., sanitizing claim on hard surfaces) or, alternatively, a description of a use site and the performance standards that apply (e.g., fabrics and textiles, air sanitizers).

2. A reference to the appropriate Guideline for an acceptable test protocol. The performance standards are based upon testing in accordance with the test methods of the Pesticide Assessment Guidelines, Subdivision G, or "its equivalent." The term "equivalent" is defined in § 156.441 to mean a protocol or method that accomplishes the purposes of the cited Guidelines, and that provides data equal in quality and completeness for EPA assessment as that of the cited Guideline. With respect to antimicrobial protocols, an equivalent protocol or method must be validated by multiple laboratories studies that demonstrate equivalency.

The term "Guidelines" is defined to include both the Pesticide Assessment Guidelines, Subdivision G, and the OPPTS Harmonized Guidelines. For antimicrobial efficacy testing, these differ only in the numbering and formatting of the Guidelines. Ultimately, the OPPTS Guidelines are intended to supersede the OPP Guidelines. EPA expects the Harmonized Guidelines to be issued before this rule is promulgated. Therefore, in this proposal we have included references only to those updated Guidelines. A copy of the latest draft of the Harmonized Guidelines for Antimicrobial Performance (810 series) is included in the public docket. If the Harmonized Guidelines are not final and available at the time of promulgation, EPA will substitute references to the existing Pesticide Assessment Guidelines in the final rule.

3. A statement of the acceptable claim(s) that may be made on labeling of a product that meets the performance standard. Typically, explicit terminology or wording is provided, which must be used to ensure uniformity of claims. In this respect, § 156.442 would clarify that EPA requirements for specific terminology also authorize grammatical variations on that iterminology, or its use in statements and phrases. For example, when EPA specifies that an acceptable claim is as a "tuberculocide," a product would be permitted to use the term "tuberculocidal" in a statement or phrase describing the activity of the product.

4. Any restrictions or limitations upon use of the claim. For example, proposed § 156.455, *Air sanitizers*, states that an air sanitizer must bear a statement that accurately

describes the limited nature of the sanitizing claim.

5. In some cases, a description of unacceptable claims. Generally, both restrictions on claims and unacceptable claims are needed to ensure that users, who may have broader expectations of efficacy than the product demonstrates and the labeling conveys, are fully informed of product limitations. For example, proposed § 156.455, *Air sanitizers*, specifies that an air sanitizer may not make claims as a sterilant, disinfectant or germicide.

Proposed subpart W does not contain all required use directions for antimicrobial public health products. It contains only the specific performance standards and closely related restrictions and limitations on labeling claims derived from those standards. Adequate use directions for achieving expected efficacy require detailed instructions that vary depending on the type of product, use site and target organism, and must be determined on a case-by-case basis. Particularly for antimicrobial pesticides, use instructions must reflect very specific test parameters keyed to sites of use. For example, the presence of soil or moisture on a surface may affect the ability of a product to perform, and must be accounted for both in efficacy testing and in labeling use directions. These more detailed use instructions are contained in Subdivision H, Labeling Requirements for Pesticide Use Directions, Antimicrobial Products.

XIII. Other Labeling Revisions

A. Use Dilution Labeling

FIFRA sec. 3(c)(9)(D) provides that antimicrobial products that are or may be diluted for use may bear a different "statement of caution or protective measures" for the recommended diluted solution than for the concentrate, provided that adequate data have been submitted to support the proposed statement and the label provides adequate protection for exposure to the diluted solution of the pesticide. The Agency has developed policy and procedural guidance pertaining to use dilution labeling, and will apply the policy to all pesticide products, not just antimicrobial products as required by FIFRA. Today's proposal would modify current regulations in part 156 to provide specifically for use dilution labeling.

1. Data Requirements. EPA intends to specify in a future part 158 proposal the data required to support use dilution labeling for antimicrobial products.

The data needed to support use dilution labeling changes consist of data on acute toxicity of the diluted product. If a product is diluted with water, systemic toxicity (acute oral or dermal toxicity) categorization can be supported by calculations from the concentrated product. In general, systemic toxicity categories differ by a factor of 10. Therefore, in most cases, if dilutions are an order of magnitude or more, the toxicity category for a particular route of exposure can be expected to be the next lower category (Category I is highest). For example, if the concentrated product toxicity category is II and the product as used is diluted at least 10-fold, the diluted product should be in toxicity category III; if it is diluted more than 100-fold, the diluted product should be in toxicity category IV.

On the other hand, label statements triggered by skin or eye irritation or dermal sensitization must be supported by new or cited studies. Calculations are not acceptable because irritation and sensitization effects do not necessarily correlate directly with the degree of dilution. In some cases, a diluted product may be more irritating than the concentrated product. Data may be cited if another registered product (such as a ready to use formulation) with a composition similar to the diluted product is supported by acceptable data.

In all cases in which the diluent is other than water, data must be submitted, since diluents other than water may themselves be toxic.

2. Permitted use dilution labeling. EPA proposes to expand its current labeling regulations in 40 CFR part 156 to address opportunities for use dilution labeling. Currently § 156.10 requires that a product be labeled with information on the product as distributed and sold. The product that is marketed to users may be a concentrate product with directions for use dilution, or may be a ready-to-use product requiring no dilution. In many cases, a concentrate product as diluted will be substantially similar in composition and hazards to a ready-to-use product. It makes

sense, then, that registrants should be permitted to provide additional information on precautions and protective measures for the diluted product. At the same time, the addition of statements appropriate for the product as diluted should not be allowed to detract from or mislead the user as to the hazards of the product in its undiluted form.

EPA believes that the "statement of caution or protective measures" referred to in FIFRA sec. 3(c)(9)(D) includes the first aid or practical treatment statement, the human (and animal) precautionary statements, and various personal protective equipment statements. EPA believes that a "statement of caution" does not extend to the signal word (DANGER, WARNING, or CAUTION), word POISON and skull and crossbones, or child hazard warning ("Keep Out of Reach of Children"), which should reflect and alert users to the typically higher hazards associated with the concentrate product.

If the labeling allows a range of dilution, EPA would permit use dilution labeling only for the most concentrated dilution. EPA believes that there is little value in multiple sets of precautionary statements reflecting various levels of use dilution, and that product users would find multiple statements cluttering and confusing.

Because the concentrate product typically presents higher hazards than the diluted product, EPA would not permit dilution-based statements either to substitute for or modify existing statements for the concentrate product. Rather, EPA would permit additional statements that augment the information for the concentrate product to appear following the concentrate product information. For example, the wording in italics could be added to precautionary or first aid statements:

> HAZARDS TO HUMANS. "Causes substantial but temporary eye injury. Do not get in eyes or on clothing. Wear goggles or face shield. Wash thoroughly with soap and water after handling. Wash contaminated clothing before reuse. *After product is diluted, goggles or face shield are not required."*
>
> FIRST AID. "If on skin: Take off contaminated clothing. Rinse skin immediately with plenty of running water. Call a doctor or poison control center for further treatment advice. *If diluted product gets on skin, medical attention is not required."*

Separate statements could also be used, with appropriate headings for "Concentrate" and "Diluted product" or similar wording.

B. Reorganization of Labeling Regulations

EPA proposes to reorganize § 156.10(h), which describes labeling requirements pertaining to hazard statements, to upgrade its structure. EPA believes that this long overdue reorganization is needed to accommodate the new use dilution provisions, and to improve the readability of the human hazard and precautionary sections of its labeling regulations. Ultimately EPA intends to upgrade part 156 entirely, but at present is doing so only as part of other regulatory proposals that affect labeling.

EPA has already proposed to upgrade the structure of its use direction labeling requirements as part of its proposal on Pesticides and Ground Water State

Management Plans (June 26, 1996; 61 FR 33260). That proposal would create subpart G to contain directions for use. Today's proposal carries this organizational upgrading one step further. EPA proposes to create new subpart D in part 156 (comprising §§ 156.60 through 156.79), and locate in it all human hazard and precautionary statements, including physical and chemical hazards. Environmental hazard and precautionary statements, currently located in § 156.10(h)(2)(ii) would be located in new subpart E.

In reformatting, EPA has reworded the provisions of current 156.10(h) for clarity, and is proposing several minor changes:

1. Section 156.64 would eliminate the requirement that a product in Toxicity Category IV by all routes of exposure bear a signal word. Currently, products in Toxicity Categories III and IV bears the same signal word, CAUTION. Products in Toxicity Category IV are of minimal toxicity, and EPA believes that a signal word is not necessary for effecting the purposes for which the product is intended. Indeed, the same signal word for two different categories of toxicity may contribute to misunderstanding of the hazards of products in both categories.

In recent research conducted under the Consumer Labeling Initiative, users of several types of consumer products tended to ascribe a higher level of hazard to products bearing the signal word CAUTION than to products bearing no signal word at all. Thus the signal word CAUTION on a Category IV product has the potential to be misunderstood. Users may consider all products bearing the signal word CAUTION as similar in toxicity, even though those in Toxicity Category IV pose negligible hazard while those in Category III pose moderate but real hazards.

The hierarchical Toxicity Category scheme is designed to allow distinctions to be made among products based on acute toxicity. Signal words assigned to the four toxicity categories are intended to allow users to make informed choices about the risks of the products they purchase. Having the same signal word for two categories runs counter to this goal. The hierarchy of product toxicity would be easier to convey on labeling if each category were clearly differentiated from another. Absent a new signal word to assign to Toxicity Category IV products, EPA proposes to eliminate the signal word entirely. The label would still be required to bear the child hazard warning.

2. Section 156.64 would include limitations on the use of signal words on the labeling. That section would proscribe use of more than one signal word, use of a signal word reflecting use dilution toxicity, or use of a higher signal word than assigned to the product. These reflect longstanding policy not previously contained in regulations.

3. Section 156.66 would clarify that the child hazard warning, "Keep Out of Reach of Children" is not always appropriate for all products, and that EPA may require or permit an alternative wording of the statement. This change would codify existing

policy.

4. Section 156.68 would require the heading "First Aid," instead of the currently required "Practical Treatment," for the statement regarding emergency treatment by a user to mitigate pesticide exposures. This change was recommended in the Consumer Labeling Initiative Phase I Report (September 30, 1996), in which consumer interviews identified label improvements for consumer pesticide and non-pesticide products.

5. Section 156.68 would also require that a first aid statement appear on the front panel of the label for each product in Toxicity Category I, including for the first time eye and skin irritation effects. Currently, the statement is required on the front panel only for products in Toxicity Category I based upon systemic effects.

EPA believes that the current distinction between systemic and irritation effects is not justified. The corrosive effects associated with exposure to a Toxicity Category I skin or eye irritant are potentially irreversible, and EPA believes that information on mitigating those effects should be clearly and immediately available to the user. Logically, then, first aid measures for skin irritation should be as prominently located on the label as those for dermal toxicity. Location on the front panel affords the greatest prominence to first aid statements.

6. In creating new subpart E in which to locate environmental hazard and precautionary statements, EPA has included in a general section (§ 156.80) introductory language describing the location and type size of environmental hazards statements.

C. Updated Toxicity Categories

EPA had intended to propose to update its current Toxicity Categories for acute hazard labeling. The Toxicity Categories in § 156.10(h) were established in 1975 and are no longer current. In September 1998, however, the United States agreed in principle with the Organization for Economic Cooperation and Development (OECD) to harmonize internationally the classification systems for a number of hazard criteria, including acute toxicity. The proposed classification scheme differs markedly from EPA's current scheme, both in the number of and criteria for acute toxicity categories. Implementation plans for the new scheme are intended to be developed by the year 2000.

In light of the proposed internationally harmonized scheme, EPA has decided not to propose to update its toxicity categories. At best, updating would be an interim step, which would be superseded in 2-3 years by U.S. implementation of the new scheme, which itself will be a major undertaking for the pesticide industry.

XIV. Chemical Sterilants

A. Liquid Chemical Sterilants Excluded by Statute

FIFRA sec. 2(u) specifically excludes from the definition of "pesticide" liquid chemical sterilants (and their subordinate disinfectant claims) for use on a critical or semi-critical device. This change in FIFRA was effective on August 3, 1996, and supersedes the interim guidance outlined in PR Notice 94-4 (June 30, 1994). That notice pertains to registration procedures for liquid chemical sterilant products affected by the June 3, 1993 Memorandum of Understanding (MOU), as amended, between EPA and FDA. In accordance with the MOU, EPA was preparing a rule to exempt such products from FIFRA regulation under section 25(b), which would have yielded regulatory jurisdiction solely to FDA. That proposal is no longer needed since the jurisdictional change was accomplished statutorily.

Under the MOU, FDA also agreed to issue a regulation exempting general purpose disinfectant products from the requirement for pre-market approval under FFDCA sec. 510(k), acknowledging that EPA oversight through registration was sufficient for public health purposes. That proposal was issued on November 6, 1998 (63 FR 59917).

The effect of the exclusion under FIFRA is that such products are regulated solely by FDA as "devices" as defined in section 201 of the FFDCA. EPA has issued a notice to registrants of affected sterilant products (PR Notice 98-2, January 15, 1998), informing them of the change in regulatory jurisdiction. Today's proposal will codify in new § 152.6 the statutory exclusion for liquid chemical sterilants, though codification is merely a convenience for the regulated community and is not necessary for the exclusion to be effective.

Codification of the liquid chemical sterilant exclusion does not change the interim measures outlined in PR Notice 94-4 for general purpose disinfectants, nor does it affect liquid chemical sterilant products intended for use on non-medical devices, such as those intended for use solely on environmental surfaces, or those which are intended for veterinary purposes.

B. Non-liquid Chemical Sterilants Exempted by Regulation.

EPA proposes further to use its authority under FIFRA sec. 25(b) to exempt from FIFRA regulation the following additional antimicrobial product types: (1) non-liquid chemical sterilants for use on critical/semi-critical devices, except ethylene oxide; 2) non-liquid chemical sterilants bearing, in addition to sterilization claims, subordinate disinfectant claims for use on critical/semi-critical devices.

FQPA modified the definition of "pesticide" in FIFRA sec. 2(u) so as to grant FDA exclusive jurisdiction over *liquid chemical sterilants* for use on *critical/semi-critical devices*. Congress did not, however, address non-liquid chemical sterilants, which have similar uses as liquid chemical sterilants. In fact, under FFDCA sec. 201(h), FDA regulates *all* chemical sterilants used on *all* medical devices, not just liquid chemical sterilants on critical and semi-critical devices. In modifying FIFRA, Congress affirmed that FDA jurisdiction under FFDCA sec. 510 was an adequate means of regulating

these sterilant products, and that dual oversight with EPA was unnecessary to protect the public health.

FIFRA sec. 25(b) authorizes EPA, by regulation, to exempt a pesticide from any or all provisions of FIFRA if the pesticide is adequately regulated by another Federal agency. EPA believes that Congress' expression of the adequacy of FDA's approval process for liquid chemical sterilants and their subordinate disinfection claims on critical/semi-critical devices as a statutory matter is an adequate basis for EPA to determine that non-liquid chemical sterilant products are adequately regulated by another Federal agency.

C. Antimicrobial Products Neither Excluded nor Exempted

1. Any claims on non-critical medical devices. EPA does not propose to exempt sterilants or disinfectant products used on non-critical medical devices from FIFRA regulation. Non-critical medical devices potentially cover a wide array of items and surfaces, such as blood pressure cuffs and bedpans. EPA and FDA currently share jurisdiction over products used on non-critical medical devices. However, under its 1993 MOU with FDA, EPA and FDA agreed to an approach under which FDA would grant sole responsibility for products used on non-critical medical devices to EPA. FDA has recently proposed a regulatory change that would accomplish this transfer of responsibility .

2. Any claims on non-medical devices. EPA has sole jurisdiction over all claims on non-medical devices. These products are not regulated jointly with FDA.

The combination of the statutory exemption for liquid chemical sterilants and the exemptions proposed under FIFRA sec. 25(b) would give FDA sole jurisdiction over all chemical sterilants (except ethylene oxide), together with their subordinate level disinfection claims for use on al lcritical and semi-critical medical devices. Exempting from FIFRA coverage additional sterilants and uses and consolidation of regulatory jurisdiction with FDA will eliminate dual regulatory requirements and unnecessary paperwork requirements.

Table 5 sets out concisely the status of chemical sterilants and other antimicrobial products used on medical devices, and the statutory and regulatory transfers that are occurring for liquid and non-liquid chemical products. Where the table indicates “no change” in the last column, the jurisdiction has not changed by statute, and EPA is not proposing any regulatory change.

TABLE 5--ANTIMICROBIAL PRODUCTS USED ON MEDICAL DEVICES

Product	In this form--	For this use--	Is under the Jurisdiction of--	By Virtue of--
Sterilant + any subordinate level disinfectant claim (except ethylene oxide)	Liquid	Critical/semi-critical medical devices	FDA	Statutory exclusion
		Non-critical medical devices	FDA/EPA	No change
		Sites other than medical devices	EPA	No change
	Non-liquid	Critical/semi-critical medical devices	FDA	FIFRA exemption
		Non-critical medical devices	FDA and EPA	No change
		Sites other than medical devices	EPA	No change
Products bearing disinfectant or sanitizer claims only	All forms	Non-critical medical devices	EPA and FDA	No change
		Sites other than medical devices	EPA	No change

D. Ethylene Oxide

Ethylene oxide is a gaseous form of sterilant, and thus was not transferred to FDA jurisdiction by statute. EPA does not propose to exempt the sterilant ethylene oxide because, in contrast to the other non-liquid sterilants that would be exempted, ethylene oxide use is not limited to medical and hospital use. Ethylene oxide is used as a fumigant for foods, particularly for fumigation of whole spices, a use regulated by no other Agency except EPA. Thus, even if EPA were to exempt the ethylene oxide sterilization use on critical/semi-critical devices, EPA would retain significant oversight over ethylene oxide for other uses. It makes sense, then, for EPA to retain jurisdiction over the sterilant use of ethylene oxide on medical devices.

XV. Nitrogen Stabilizers

A. Nitrogen Stabilizers are Regulated as Pesticides

FQPA expanded the FIFRA definition of "pesticide" to include nitrogen stabilizers, but by definition in FIFRA sec. 2(hh) "nitrogen stabilizer" excludes certain substances. Two named substances (dicyandiamide and ammonium thiosulfate) are excluded outright. Other substances are excluded if they meet the criteria in section

2(hh)(3): they were introduced into commercial agronomic use by January 1, 1992, without being registered under FIFRA, and thereafter have not made specific claims of "prevention or hindering of nitrification, denitrification, ammonia volatilization [or] urease production" (collectively referred to in this discussion as "nitrogen stabilization claims"), except where required to do so under State pesticide regulations.

EPA proposes to add to new § 152.6 those substances that are not nitrogen stabilizers by statutory definition and therefore not regulated as pesticides when used for nitrogen stabilization purposes. All other nitrogen stabilizer products are regulated as pesticides under FIFRA. This unit discusses how EPA will determine which nitrogen stabilizers it will treat as pesticides.

B. What is a Nitrogen Stabilizer?

1. Action on soil bacteria. To be a nitrogen stabilizer in the first instance, a product must accomplish the purpose of nitrogen stabilization through "action upon soil bacteria." Clearly, this phrase excludes fertilizer products, which increase soil nitrogen by simple addition of nitrogen-containing substances rather than any soil bacterial action. However, any product that enhances soil nitrogen availability by affecting the soil bacteria is a nitrogen stabilizer, regardless of whether it also functions as a fertilizer after action on soil bacteria. Such dual products that function both as nitrogen stabilizers and fertilizers are regulated under FIFRA if they meet the other statutory criteria for nitrogen stabilizers.

2. Date of introduction into commerce. The first criterion pertains to the date of introduction of the product into commerce. Section 2(hh) specifies January 1, 1992, as the date before which the product must have been in “commercial agronomic use” but not registered as a pesticide (as well as the date after which no specific claims of nitrogen stabilization must have been made in connection with its sale and distribution; see below). EPA can verify from its records what products were registered before January 1, 1992 (these are nitrogen stabilizers that must continue to be registered).

EPA interprets "commercial agronomic use" to mean that a product is being distributed and sold at the wholesale and retail levels. A product that is being distributed only in a limited or restricted way in preparation for full marketing is not considered to have achieved commercial marketing status.

3. Specific claims. The second criterion relates to the claims made for the product. The statute does not define what is meant by a "specific claim of prevention or hindering of the process of nitrification, denitrification, ammonia volatilization [or] urease production." Moreover, there is no explanatory legislative history to guide EPA in discerning Congressional intent. Therefore, EPA is interpreting the phrase in a common sense manner.

Nitrification, denitrification, ammonia volatilization and urease production denote specific undesirable actions of soil bacteria with the result that nitrogen availability is

decreased. Clearly, any product that uses these terms on the label is making a "specific claim" of mitigating that effect. However, other claims which focus only on the end result of nitrogen stabilization (increased/prolonged availability of nitrogen) are also used on product labels. EPA identifies examples of these phrases in proposed § 152.6(b)(4). The phrases listed in that section, to the Agency's knowledge, could be used to describe only two functions of products--either the fertilizer effect of addition of slow-release nitrogen-containing substances, or the pesticidal effect on soil bacteria that is nitrogen stabilization and has the same end result.

Although these label claims could theoretically be used to describe fertilizers, EPA believes that they are in practice claims of nitrogen stabilization rather than fertilizer claims, for the following reasons. First, fertilizer products are already excluded from FIFRA regulation by EPA's own regulations in § 152.8, and a fertilizer product need only be labeled as such (and bear no other pesticide claims) to avoid FIFRA regulation. It would make little sense for a fertilizer product to bear claims such as "increases nitrogen uptake" or "prolongs nitrogen availability" when a simple declaration as a "fertilizer" would suffice under FIFRA, and "fertilizer" is a description of such a product that would be understood by all purchasers. The only other plausible use of these ambiguous claims relates to nitrogen stabilizing effects on soil bacteria.

More telling is EPA's experience in evaluating such products. A first-hand examination of the labeling and ingredients declaration of a product is the most reliable method to determine if products with such claims are to be regulated under FIFRA. An examination of this sort is similar to the process used for many years to determine the pesticide/non-pesticide status of plant regulators (pesticide) versus fertilizer (non-pesticide) products. In each instance that EPA has examined a product bearing a claim such as described in § 152.6(b)(4), EPA has determined that the product was, in fact, functioning as a nitrogen stabilizer, and that the product composition was consistent with an expected nitrogen stabilization purpose rather than, or in addition to, a fertilizer purpose.

Moreover, such an interpretation of indirect claims is in keeping with EPA's past and current policies on nitrogen stabilizers. EPA's policy has been to treat claims that indicate pesticidal intent as pesticide claims that subject the products to regulation under FIFRA. Therefore, EPA proposes to treat any claim that states or implies that the product will prevent or hinder nitrification, denitrification, ammonia volatilization, or urease production as a claim that brings the product under the purview of FIFRA as a nitrogen stabilizer. If a product functions solely as a fertilizer or a slow- or delayed-release fertilizer, is labeled as such with explanatory information on the method used to accomplish any delayed- or slow-release action (e.g., by encapsulation) and bears no additional claims that appear to be nitrogen stabilization claims, it would not be considered a pesticide.

EPA believes that to do otherwise would create an administrative and enforcement inequity that could potentially undermine the intent of the statute to the point where it would have little practical effect. The purpose of incorporating nitrogen

stabilizers into the definition of "pesticide" in FIFRA sec. 2(u) is to regulate certain nitrogen stabilizers as pesticides. If EPA were to interpret the Act to limit the regulatory coverage of nitrogen stabilizers to products that use the magic words "nitrification," "denitrification," "ammonia volatilization," or "urease production," while ignoring other language that makes equivalent but differently phrased claims, a product that Congress intended to be regulated could escape FIFRA regulation merely by using a "code phrase" that conveys the same meaning as these terms. Arguably, under such a restrictive interpretation, the only nitrogen stabilizers covered by FIFRA might be those already registered as of January 1, 1992. EPA believes that Congress could not have intended to extend coverage of FIFRA to nitrogen stabilizers, only to exclude most or all of those products by a mere turn of phrase.

4. State exclusion. Congress did provide a specific exclusion for statements that are required by State legislative or regulatory authorities. A product that makes a claim of nitrogen stabilization in its labeling or other materials only because of a State requirement is not thereby brought under FIFRA regulation. Congressional intent is clear: Federal regulatory authority over nitrogen stabilizers should not be enlarged by actions of the States. Nor does EPA believe that Congress intended that a product that triggered Federal regulation by making nitrogen stabilizer claims be removed from regulation by subsequent action of a State. Proposed § 152.6 therefore makes clear that the State requirement for labeling must be a pre-existing one, that is, in place prior to the assertion of nitrogen stabilizing claims by the seller or distributor.

Moreover, a product for which nitrogen stabilization claims are made because of a State requirement is nonetheless subject to FIFRA regulation if at any time since January 1, 1992, nitrogen stabilization claims have been made for the product with respect to its distribution and sale in another State that does not have such a requirement. Sale or distribution of such a product in any State, including the State which imposed the labeling requirement, is subject to the provisions of FIFRA.

The producer of a product who claims eligibility under this exclusion would need to maintain sufficient records to clearly demonstrate that, as of January 1, 1992, the product was being commercially distributed and sold (sales records, for example), and that no nitrogen stabilization claims were made after that date (dated copies of labeling and advertising, for example). These records are maintained by producers as a normal business practice, so no additional recordkeeping would be required by this proposal.

XVI. Notification of Registration Changes

A. FQPA Modifications

EPA proposes to modify its current notification procedures for antimicrobial products to conform to those established under FIFRA sec. 3(c)(9). The statutory provisions requiring these changes are discussed in Units IV.I. and V.B.

Prior to FQPA, FIFRA did not provide a notification scheme. In 1988, EPA implemented a regulatory notification framework (contained in § 152.46), under which EPA determines acceptable modifications to registration that may be made by notification. The types of acceptable notifications are set out in direct notices to registrants, together with the procedures for submitting notifications.

FQPA modified FIFRA with respect to notifications for antimicrobial pesticides only, in both substance and procedure. For the first time, FIFRA establishes a statutory right for antimicrobial registrants to make certain types of changes by notification. Specifically, a registrant may modify the labeling of an antimicrobial pesticide product to include relevant information on product efficacy, product composition, container composition or design or other characteristics, that do not relate to any pesticide claim or pesticidal activity. Further, FIFRA sets up a procedure for antimicrobial notifications that holds both registrants and EPA to a high degree of accountability.

FIFRA sec. 3(c)(9) became effective on August 3, 1996; today's proposal would codify the procedures of the Act that are already in effect. Neither current regulations nor this proposal address the types of actions that may be accomplished by notification.

The notification provisions of the Act apply only to antimicrobial products. As a policy matter, EPA could extend both the types of notifications and the procedures for notifications to other products. After consideration, EPA has decided to allow non-antimicrobial registrants to avail themselves of the new types of notifications provided by FIFRA sec. 3(c)(9), but will not propose changes in its current procedures for notifications for such products. Although EPA believes that the new statutory process for antimicrobials is superior in some ways to the existing notification scheme, it is reluctant to add an additional procedural layer to a system that appears to work well as currently administered.

Consequently, after the effective date of this rule, EPA would have in place two notification schemes (antimicrobials/other pesticide products), but would have a unified set of notification actions. After the effective date of this rule, antimicrobial registrants would be required to follow the notification procedures of § 152.446 only; they would not be permitted to follow the current procedures in § 152.46. EPA welcomes comment on whether the notification procedures for antimicrobials should be adopted across-the-board. If persuaded by commenters that there are benefits without undue costs in making the procedures for notifications uniform for all products, EPA could, in the final rule, adopt the procedures across-the-board. If it does so, EPA would simply adopt the provisions of § 152.446 to replace those currently in § 152.46.

Although EPA does not propose to apply the new procedures to all products, it believes that the types of notifications permitted by FIFRA sec. 3(c)(9) should be extended to all products rather than limiting them to antimicrobials. Doing so does not require that EPA modify its regulations in § 152.46, since permitted notifications are detailed in direct notices to registrants (PR Notices), a practice EPA would continue.

Current permitted notifications are specified in PR Notice 98-10, issued October 22, 1998.

B. Comparison of Current and New Procedures for Antimicrobial Products

This unit describes the new procedures for antimicrobial product notifications and compares them to the current procedures for all other products, which are not proposed for change. The significant differences between antimicrobial procedures and current notification procedures in § 152.46 are that:

1. Registrants who submit antimicrobial notifications must wait 60 days after submission before distributing or selling the modified product. Registrants of other products may distribute or sell immediately upon submission.

The new scheme offers an eminently practical solution for the uncertainties of compliance and enforcement in the current notification process. Under the current scheme, a registrant who ships immediately upon notification runs the risk that EPA might thereafter determine the notification is improper, and the product would be in violation of FIFRA. Because FIFRA sec. 3(c)(9) prohibits sale and distribution of a modified product for 60 days after submission, but requires Agency action within 30 days (see below), there will always be some period of time after the Agency's decision before an antimicrobial product can be shipped legally. There is no possibility (as exists under the current scheme) that a registrant will ship an antimicrobial product only to have the Agency disapprove the notification. The benefit of certainty is somewhat offset by the fact that an antimicrobial registrant must wait before shipping. However, EPA proposes in § 152.446 to allow shipment at any time after receipt of approval by the Agency (30 days), thereby almost halving the 60-day waiting time.

2. EPA is obligated to disapprove antimicrobial notifications it finds unacceptable within 30 days after receipt. Under the current process, EPA's goal is to make its determination within 30 days, but it is not required to do so.

The new process involves some increase in resources and time on EPA's part. Requiring a review and specific disapproval decision within 30 days of receipt is more demanding than the current scheme which lacks a decision deadline. Nonetheless, antimicrobial notifications are currently being processed within 30 days, so EPA anticipates little pressure on its current antimicrobial program resources to accommodate the 30-day decision deadline.

3. EPA may require substantiating information for an antimicrobial notification. Current EPA regulations in § 152.46 do not explicitly mention substantiation. EPA proposes that antimicrobial registrants be required to retain, and submit upon request, substantiating information for each modification. Substantiating information might be required to be submitted if the registrant objected to the Agency's disapproval of his notification. The provision for substantiation of claims for antimicrobial products offers

EPA greater assurance that the claims are in fact accurate, and can be verified objectively or scientifically.

4. Antimicrobial registrants may formally object to the Agency's disapproval of an antimicrobial notification. Current § 152.46 contains no provision for appeal of an Agency disapproval. The availability of an administrative appeals process, if used frequently, would increase resource needs to administer the process. However, EPA anticipates few appeals since the types of notifications permitted by the statute are relatively straightforward decisions for which the current notification scheme was designed.

XVII. Conforming and Organizational Revisions

A. Changes in Definitions

EPA is proposing to modify, delete or add a number of definitions to § 152.3. Definitions located in § 152.3 apply to all pesticide applications, including antimicrobial applications. The definition of "pesticide" would be deleted because it has become so long and complicated in the statute itself that it adds no value to reiterate the definition in regulations. The definition of "active ingredient" would be modified to conform to the change made by FQPA. Definitions to be added include the following:

1. "Antimicrobial pesticide," to allow reference to new subpart W. The definition proposed here interprets the statutory definition to clarify and give practical meaning to the exclusions from the definition for "wood preservative," "antifoulant paint product," "fungicide for agricultural use" and "aquatic herbicide."

2. "Applicant," "registrant" and "application for registration," to create concise terms that cover both new and amended registrations.

3. "Complete application." This definition is being added to apply to all pesticide applications because a number of FIFRA provisions (not just those for antimicrobial products) depend upon the submission of a "complete application," including: (1) the timeframes for all "fast-track" applications under section 3(c)(3)(B); (2) the priority given to review of minor use applications under section 3(c)(3)(C); and (3) the priority given to so-called "safer" pesticides under section 3(c)(10). For antimicrobial pesticides, § 152.450 contains detailed information on what constitutes a complete application.

4. "Fast-track application," to formalize the term widely used by the Agency and the regulated community for applications under FIFRA sec. 3(c)(3).

5. "Nitrogen stabilizer," to include the statutory term here for convenience.

B. Exclusions and Exemptions under FIFRA

EPA proposes to compile in one location in its regulations the various exclusions that have accumulated in FIFRA over the years. Exclusions from FIFRA regulation are statutorily designated substances that are not to be regulated under FIFRA. Readers should note that "exclusions" do not include exemptions granted under FIFRA sec. 25(b), which are pesticides specifically removed from FIFRA regulation by Agency action.

Several exclusions already exist in FIFRA, and are identified in current regulations. These include:

1. Substances used against organisms that are not "pests" by definition in FIFRA sec. 2(t), such as "viruses, bacteria and other microorganisms on or in living man or other living animals."

2. Substances that are not "pesticides" by definition in FIFRA sec. 2(u), including new animal drugs and animal feeds containing new animal drugs.

3. Substances that indirectly are not "pesticides" by virtue of being excluded from definitions of substances that are pesticides. For example "vitamin-hormone horticultural products" are excluded from the definition of "plant growth regulator" in FIFRA sec. 2(v).

FQPA amended FIFRA to add two additional exclusions for substances that are not to be regulated under FIFRA. Because the existing exclusions are scattered in FIFRA and have been expanded by FQPA, EPA believes it would be useful and convenient to consolidate them in one location in its regulations. Accordingly EPA proposes to create new § 152.6 and to include in it both existing and new exclusions.

Existing exclusions, which have not been altered, include those in § 152.8 for pests of living man and animals (human and animal drugs) and various soil amendment products, in § 152.20 for human drugs and in § 152.25 for vitamin hormone products. New exclusions include those for certain liquid chemical sterilants and certain nitrogen stabilizer products. EPA believes that proposed § 152.6 contains all exclusions provided by statute or existing regulations. If EPA finds that it has inadvertently omitted any exclusions provided by statute, it will in the final rule add them to § 152.6.

XVIII. Consultations During the Development of this Proposal

FIFRA sec. 3(h) requires that EPA, in developing this proposed regulation, " solicit the views from registrants and other affected parties to maximize the effectiveness of the rule development process." EPA has consulted, and maintains an open dialogue with, a number of interested parties, both in establishing the streamlined

antimicrobial program itself and in developing this proposal.

A. Stakeholder meetings

Stakeholder meetings were begun shortly after enactment of FQPA--the first was in November 1996--with a view to engaging the antimicrobial industry (which is largely composed of small businesses), public health, consumer and environmental groups, in discussions and suggestions that could be implemented in the rule. Since then, EPA has held a number of open public meetings, approximately every quarter, to discuss issues arising from the development of the antimicrobial rule and the administration of the antimicrobial registration program. These open meetings have been announced in the
Federal Register and have been attended by registrants, trade associations representing antimicrobial producers and users, other Federal agencies and environmental and consumer groups. Information about the meetings and summaries have been placed in a public docket (OPP docket control #00473, located at the address given under ADDRESSES). EPA intends to conduct further meetings of this nature, and will make special efforts to continue and expand the participation of small businesses in the dialogue fostered through such meetings.

To enhance pre-proposal input into the regulatory development process, draft language for this proposal was released to the public in April 1997 and again in June 1998. Ensuing discussions and comments raised a number of issues of concern. Among them were the following:

1.. The opportunity to rebut Agency's conditions of registration. When EPA issues a registration, it often does so with conditions attached, generally labeling changes. Registrants have not had the opportunity to have EPA reconsider conditions they believed were onerous or unnecessary. EPA has now modified the proposal to allow applicants who disagree with EPA's imposition of labeling changes as a condition of registration to submit a rebuttal for consideration.

2. A shorter review period for resubmissions. Industry was concerned that EPA might choose to start its review clock over for minor resubmissions to complete an application or respond to Agency questions. In response, EPA is proposing a specific new category of shortened review period for "qualifying resubmissions." This new category would shorten the review period that would otherwise apply by 30 days for applications with review periods of 120 days or less. EPA estimates that approximately 75% of antimicrobial applications each year would have review periods of 120 days or less, and would benefit from this provision.

3. How EPA would deal with indications of product lack of efficacy. EPA had considered a scheme whereby applicants would agree to accept as a condition of registration the imposition of a variety of measures if their product was found to be inefficacious after registration. Industry was concerned about the vague nature of

EPA's proposal, and viewed it as potentially costly. As a result, EPA has scrapped this scheme, and developed a new one (the sunset provision in § 152.458), to respond to their concerns.

B. Workshops

To complement the stakeholder meetings and extend their approach to stakeholder involvement to a larger group of participants, on January 8-9, 1997, EPA held a highly successful two-day antimicrobial regulation workshop attended by over 300 participants. At a number of plenary sessions and small discussion groups, EPA explored with participants issues such as improving and streamlining the registration process for antimicrobial products, self-certification, harmonization with States and the international community, applying for registration, and antimicrobial data requirements. A second workshop was held on June 15-16, 1998 and was attended by an even larger group of stakeholders. A major trade association with extensive small business membership was represented at both workshops. In addition, individual representatives of more than 15 small firms attended.

C. Food and Drug Administration

FQPA modified both FIFRA and FFDCA in ways that either explicitly or effectively transferred regulatory authority over a number of pesticides between EPA and FDA. As a result, EPA has consulted frequently with FDA in preparing this proposal with respect to liquid chemical sterilants (see Unit. XIV) and the transfer of regulatory jurisdiction over certain food use antimicrobial residues back to FDA (see Unit XI).

D. Canada

In the fall of 1996, EPA held discussions with the Pest Management Regulatory Agency of Health Canada, which is the Canadian government agency responsible for regulation of certain antimicrobial pesticides in Canada. These consultations focussed primarily on Canada's system of categorizing antimicrobial pesticide types, its administrative procedures that EPA might adopt to streamline, simplify and accelerate the Agency's procedures, and ways to harmonize data requirements for antimicrobial products.

Although the majority of the discussions targeted administrative rather than regulatory changes, EPA has included in this proposal expanded application contents (§ 152.450) that will, in addition to assisting U.S. regulators of antimicrobial pesticides, foster harmonization of application reviews between Canada and the U.S. For example, the requirement that an applicant supply copies of available data reviews conducted by other countries (such as Canada) will contribute to more efficient regulation of antimicrobial products. In addition, EPA's rigorous application of completeness criteria as a resource management tool mirrors that of Canada.

XIX. Table of Affected Sections

Because today's proposal covers myriad and diverse topics that affect several portions of the Code of Federal Regulations, EPA has summarized in Table 6 below all parts and sections for which additions or changes are being proposed today.

TABLE 6--CFR SECTIONS AFFECTED BY PROPOSAL

CFR PART OR SECTION NUMBER	TITLE	PROPOSED ACTION
152.1	Scope	Conforming changes
152.3	Definitions	Additions
152.6	Substances excluded from regulation by FIFRA	New
152.8	Products that are not pesticides because they are not for use against pests	Material moved to 152.6
152.20	Exemptions for pesticides regulated by another Federal agency	Material moved to 152.6; New material added
152.25	Exemptions for pesticides of a character not requiring FIFRA regulation	Material moved to 152.6
152.44	Application for amended registration	Clarification and reformatting
Part 152, subpart W (§§ 152.440 - 152.459)	REGISTRATION OF ANTIMICROBIAL PRODUCTS	New
156.10	Labeling requirements	Material moved to new subparts D and E; Conforming changes
Part 156, subpart D (§ 156.60 - 156.78)	HUMAN HAZARD AND PRECAUTIONARY STATEMENTS	Reorganized material from 156.10
Part 156, subpart E (§§ 156.80 - 156.85)	ENVIRONMENTAL HAZARD AND PRECAUTIONARY STATEMENTS	Reorganized material from 156.10
Part 156, subpart W (§§ 156.440 - 156.458)	PUBLIC HEALTH CLAIMS FOR ANTIMICROBIAL PRODUCTS	New

XX. Statutory Review Requirements

In accordance with FIFRA sec. 25(a), this proposal was submitted to the FIFRA Scientific Advisory Panel, the Secretary of Agriculture (USDA), the Secretary of Health and Human Services (HHS), and appropriate Congressional Committees. The Scientific Advisory Panel waived its review of this proposal.

A. USDA Comments

1. USDA suggested that the document include a discussion of the issues surrounding microbial pest resistance.

Response: While there is evidence that microorganisms develop resistance to antibiotics, EPA is not aware of evidence that microorganisms are developing resistance to antimicrobial pesticides. Microorganisms respond to biocidal agents, and differ markedly in susceptibility and resistance responses to agents such as disinfectants and antiseptics. Bacterial resistance to biocides is usually considered to be of two types: (1) intrinsic (a natural property of an organism); or (2) acquired (by genetic mutation or physiological adaptation). The mechanisms of susceptibility and resistance to biocides and techniques that would enhance or reduce susceptibility/resistance are not well understood and would require further research.

EPA expects that it would become aware of developing microbial pest resistance in public health products either through registrant reporting of lack of efficacy under FIFRA sec. 6(a)(2) or through the 5-year retesting program. A public health product that failed to demonstrate efficacy at the 5-year mark would be removed from the marketplace by automatic expiration of the registration.

2. USDA suggested that EPA clarify in the proposal the status of agricultural microorganisms other than fungi, for example, nematodes.

Response: EPA has revised Unit VI.C. of the preamble and the definition of " antimicrobial pesticide" in § 152.3 to clarify that an agricultural fungicide is one applied to crops or plants pre-harvest. It should be noted that nematodes are not considered microorganisms, but invertebrates, and thus would not be included in the definition of antimicrobial pesticide in any case.

3. USDA suggested that EPA standardize the review processes and times for wood preservatives and antifoulant paints.

Response: FIFRA sec. 2(mm) specifically excludes wood preservatives and antifoulant paints from the definition of "antimicrobial pesticide," and thus, with only limited exceptions, also excludes such products from the application review periods that this proposal would establish for antimicrobial pesticides. Therefore, EPA is not proposing to include wood preservatives and antifoulant paints within the scope of this regulation and its review periods. Unit VIII.H.4. contains a full explanation of when the review

periods apply to certain wood preservative products. The review periods discussed in that unit, however, do not extend to antifoulant paints.

As a practical matter, the review processes for all wood preservatives and antifoulant paints are the same regardless of where within the EPA organization they originate. The data requirements and risk assessments for such products are the same and depend on the chemical and the potential risks from its use, regardless of whether there is a statutory review period.

B. HHS Comments

HHS provided informal comments on the draft, many of which were questions, clarifications or corrections to the proposal. EPA has made changes to the draft proposal in many instances based upon their suggestions. A brief summary of their substantive comments follows.

1. HHS wanted to know the relationship between "antimicrobial pesticides" and " public health pesticides" and whether they were treated differently in the proposal.

Response: Both terms are defined in FIFRA. "Antimicrobial pesticide" is defined in FIFRA sec. 2(mm) to include, among other things, products intended to "disinfect, sanitize, reduce, or mitigate growth or development of microbiological organisms." " Public health pesticide" is defined in FIFRA sec. 2(nn) to include products for the ". . . prevention or mitigation of viruses, bacteria, or other microorganisms . . . that pose a threat to public health." An antimicrobial pesticide may be a public health pesticide if it is intended to destroy or mitigate microoganisms that pose a threat to public health.

However, there is a single standard for registrability of a pesticide in FIFRA sec. 3(c)(5), namely that the pesticide itself, or in its intended use, not cause "unreasonable adverse effects" on man or the environment, taking into account the economic, social, and environmental costs and benefits of the use of the pesticide. This is a risk/benefit balancing provision. Of significance, though, is that EPA is specifically directed to take into account the health risks posed by the disease vectors controlled by a public health pesticide when weighing its risks and benefits. Under FIFRA sec. 6(b)(2), when EPA is contemplating action against a public health pesticide based on risk, HHS should provide information on use and benefits to the Agency to inform its risk/benefit decision.

2. HHS asked about the scope of the proposed rule in relation to HHS activities under FFDCA sec. 409. The noted the statutory definition of "antimicrobial pesticide" in FIFRA, which excludes pesticides that require a clearance under either FFDCA sec. 408 or 409. They also noted that ARTCA grants jurisdiction over many antimicrobial pesticide residues pesticides that. in food to FDA (discussed in Unit XI), but it still requires registration of the pesticides under FIFRA.

Response: The definition of “antimicrobial pesticide” applies only to registration activities under FIFRA; it does not affect activities related to any FFDCA sec. 409 food additive regulation. EPA has no jurisdiction under section 409. Any action affecting the registration of an antimicrobial pesticide under FIFRA, such as cancellation or expiration under the “sunset provision,” would not necessarily require that FDA revise or revoke any food additive regulations associated with that pesticide.

A similar situation could arise if EPA has established a tolerance or exemption under section 408 for a pesticide whose registration has expired under the sunset provision. As noted in Unit IX, the sunset provision is intended to ensure efficacy of public health products, not to determine whether the tolerance fails to meet the “ reasonable certainty of no harm” standard of FFDCA. It is unlikely that the cancellation or expiration of any single product registration would trigger action to revoke the tolerance because there likely would remain other products on the market for the same use that are supported by the same tolerance or food additive regulation.

That said, EPA proposes to include all antimicrobial products in the scope of its proposed regulation. Unit VIII.B contains a full explanation of the applicability of subpart W. Under § 152.441, subpart W applies not only to “antimicrobial pesticides,” but also to antimicrobial products whose registration requires a clearance under FFDCA sec. 408 or 409. Because the proposed rule affects only FIFRA actions, however, the difference in coverage of the statutory term “antimicrobial pesticide” and the broader coverage of the proposed rule is not expected to affect HHS activities under FFDCA over those same pesticides.

3. HHS commented that EPA proposed to expand the scope of FDA authority over chemical sterilants beyond that agreed to by EPA and FDA.

Response: EPA has revised the proposal to align its provisions with FDA’s understanding of our respective responsibilities (see Unit XIV.).

4. HHS comments suggested several areas where increased EPA/FDA consultation was desirable or necessary, for example, enforcement of labeling claims for products subject to both EPA and FDA jurisdiction.

Response: EPA and HHS are in the process of developing a Memorandum of Understanding (MOU) that would address responsibilities and consultations in a number of areas. The MOU will establish a consultative process between the Agencies that will facilitate information exchange and resolution of issues. EPA expects that the consultations undertaken under the MOU will serve the various purposes noted by FDA. Currently EPA and HHS consult informally and frequently with counterparts in the Food and Drug Administration, the Centers for Disease Control, and other HHS offices on issues of joint authority and mutual interest.

5. HHS requested that EPA clarify the status under the Freedom of Information

Act of data and/or data reviews provided to other agencies if the applicant authorizes EPA to share such data.

Response: The status of data provided to another Agency under a registrant authorization would not change under FOIA because of the data sharing. A request to HHS for the release of such data would be treated the same under FOIA as a request to EPA.

6. HHS had a number of comments related to the efficacy performance standards (Part 156, subpart W).

a. Virucidal claims. HHS suggested that EPA consider selecting representative viruses with differing intrinsic resistance to antimicrobial chemicals and use those as benchmark viruses for test purposes in support of a general virucidal claim.

Response: Currently, EPA requires that each specific virus intended to be claimed on the label be tested, and identified on the labeling. EPA takes the position that there is no known database that assures that all viruses have the same susceptibility or resistance responses to antimicrobial agents, or that allows across-the-board extrapolation of results. Nonetheless, EPA has funded a 3-year research project on the use of surrogate viruses. The results from this study are currently under review.

b. Efficacy terminology. HHS noted that there are differences in terminology between EPA and HHS performance measures. HHS considers a laboratory test demonstrating product efficacy to be a test of a chemical's "potency" and not its " efficacy." HHS believes that "efficacy" is demonstrated only in the ability of an antimicrobial agent to reduce or prevent transmission of disease.
Response: EPA acknowledges these differences. In the case of antimicrobial pesticides, EPA uses the term "efficacy" to refer to laboratory testing that demonstrates " presumptive" efficacy of a product in reducing microbial populations on environmental surfaces. FIFRA specifically excludes as pests microorganisms in or on living man or other living animals (as opposed to microorganisms on surfaces to which man might be exposed). Effectiveness testing that would demonstrate performance of an antimicrobial pesticide against microorganisms in man and that would meet HHS' definition concerning actual reduction or prevention of disease is not within EPA's purview.

Based upon the laboratory tests that demonstrate efficacy for FIFRA purposes, EPA permits label claims only to the extent that the product reduces or eliminates target organisms under standard laboratory conditions or carefully defined simulated use protocols. Because EPA does not require or evaluate data on disease-related claims, antimicrobial pesticide products are not permitted to bear claims concerning reduction in transmission or prevention of disease, though they may claim the ability to reduce precursor microorganisms.

c. “Sanitization” claims. HHS requested clarification of the scope of the Agency’s policy on “sanitary” and “sanitize” as pesticide public health claims. HHS noted that a product that “sanitizes” food equipment would not be an “antimicrobial pesticide” under FIFRA sec. 2(mm) because such use would be a food use requiring a tolerance or exemption under section 408. They requested clarificaiton as to whether such a sanitizer would be subject to subpart W labeling requirements, and whether it would be a public health pesticide.

Response: Yes. A pesticide that sanitizes food equipment would be a public health pesticide because sanitization is a claim of a specific level of antimicrobial activity against microorganisms associated with public health protection. It would therefore be subject to the labeling requirements of proposed subpart W of part 156. As noted earlier, the definition of “antimicrobial pesticide” in the proposal is broader than that in the statute. EPA has revised § 156.440 to clearly state that the applicability of part 156, subpart W, corresponds to that in part 152, subpart W, which would encompass food use sanitizers.XX. Statutory Review Requirements

XXI. Regulatory Assessment Requirements

A. Executive Order 12866

Under Executive Order 12866 (58 FR 51735, October 4, 1993), entitled *Regulatory Planning and Review*, this action is not a "significant regulatory action" subject to review by the Office of Management and Budget (OMB). This proposal is not expected to have significant impacts on antimicrobial pesticide producers and would have no impacts on any other sector of the economy. Moreover, a number of its provisions, including exemptions for various antimicrobial sterilants, reduction in duplicative regulation with FDA, and mandatory review periods for antimicrobial applications, are expected to decrease costs and burdens currently associated with the registration of antimicrobial pesticide products.

EPA has prepared an economic analysis of the potential costs associated with this proposed action, which is contained in a document entitled “Regulatory Impact Analysis of the Proposed Antimicrobial Pesticide Rules.” This document is available in the public record for this action and is summarized in this Unit.

The only costs anticipated as a result of this action are the costs of compliance with the so-called "sunset provision." Under this provision, proposed in § 152.458, registration of a public health antimicrobial pesticide would expire every 5 years unless the registrant certifies, based upon efficacy and composition studies conducted within the year prior to expiration, that the product continues to meet the standards for registration. The studies required are an analysis of the product composition to confirm certified limits of the ingredients, and efficacy studies for each public health claim on the

product labeling.

The costs of the analysis and certified limits determination are estimated to be approximately $6,100 per product. The average cost of the efficacy studies is estimated to be just under $25,500 per product, based upon an average of six efficacy tests per product. The average annualized testing cost per product is $5,620. However, while all public health products would be subject to product analysis testing, only about 61% of products would be subject to efficacy testing, because some products can rely on testing developed for substantially similar products. Accordingly the adjusted annualized testing cost for products expected to actually have to conduct the testing is $3,897. The total annualized cost for both existing and new products is estimated to be $12.3 million.

In neither case are these costs expected to result in additional capital costs to applicants because such studies are currently required of applicants for registration, whether conducted by the applicants themselves, or, more typically, contracted for with outside laboratories.

The assumptions used in the analysis result in an overstatement of the costs of the rule, for the following reasons:

1. The analysis assumes that the testing requirement imposes costs effective immediately upon promulgation in 1999. However, actual costs will be imposed only as products are submitted for new or amended registration or reregistration over the next several years, on a schedule that EPA cannot predict. For a product first registered, amended or reregistered in 1999, the testing cost would be imposed only in the fourth year of registration (2003).

2. The analysis assumed that no firms were already complying with the sunset provisions that would be imposed. Based upon consultation with a limited number of small businesses, EPA estimates that approximately 11% of firms currently conduct testing that would comply fully, and others conduct testing that would comply partially. It is likely that a higher percentage of large firms would already be fully or partially complying.

All other provisions of this proposal would reduce the costs of compliance with FIFRA for producers of antimicrobial pesticides. Provisions that reduce costs include increased opportunities for notification instead of amendment of registration, elimination of dual jurisdiction with FDA, exemption of certain antimicrobial products from FIFRA regulation, more precise and clearer application and labeling information, and mandatory review periods for antimicrobial applications that are shorter than historical review times.

B. Regulatory Flexibility Act

Under the Regulatory Flexibility Act (5 U.S.C. 601 et seq.), the Agency hereby

certifies that this action will not have a significant economic impact on a substantial number of small entities. The only provisions in this proposal that would impose costs on any business, including small businesses, are the sunset provisions, discussed in Unit XXI.A.

The antimicrobial industry is largely composed of small businesses; the economic analysis for this proposal estimates that 83% of all antimicrobial registrants are small businesses. Accordingly, EPA is particularly interested in receiving comment from small businesses as to the benefits, costs and impacts of this rule.

1. Based on EPA's economic analysis, the Administrator has certfied under the Regulatory Flexibility Act that today's proposal will not impose a significant impact on a substantial number of small entities, in this case small manufacturers of antimicrobial products. Table 7 summarizes the results of EPA's Regulatory Flexibility analysis.

TABLE 7 - IMPACTS ON SMALL BUSINESSES

Level of Impact[1]	Percent of Small Firms Impacted	Number of Small Firms Impacted[2]
> 1%[3]	16.4%	139
> 3%	4.6%	39
>10%	0.7%	6

[1] Calculated as a percentage of Annual Sales Revenue.

[2] Calculated on the basis of 848 small businesses registering antimicrobial products.

[3] The totals are cumulative, that is, the >3% and >10% values are included in the >1% totals.

EPA believes that all costs and burdens of this rule are attributable to the "sunset provision" requiring periodic efficacy retesting and analysis of products after registration. In preparing for today's proposal, EPA conducted discussions with all segments of the industry, including small business (see discussion in Unit XVIII.A), and we have adopted many of their suggestions to minimize burden. We invite comment on whether there are additional accommodations specific to the sunset provision that the Agency should consider to further reduce the burden on small businesses.

2. Based on consultation with the regulated community, EPA believes that all other provisions would be both beneficial and cost-efficient to all segments of the antimicrobial industry, including small business. Specifically, EPA believes that there are overall reduced paperwork burdens and costs associated with increased notifications and exemptions from FIFRA; increased flexibility for applicants due to the many opportunities for informal consultations, rebuttals, and negotiations; greater clarity in the requirements for antimicrobial registration and product labeling; and cost savings for individual firms in obtaining registrations within the shortened review periods, allowing earlier entry into the market. We invite comment on whether there are additional accommodations we should consider that might further facilitate the

rgistration process for smal businesses.

3. Are there costs or burdens, efficiencies or savings attributable to this proposed rule that you believe have not been adequately identified and addressed? What are they and how great are these burdens or efficiencies? If you have a proposal for additional accommmodations to small business, please explain what you are proposing and provide information on costs or benefits of your approach.

For a discussion of the Agency's outreach to the antimicrobial industry, including small businesses, and changes to this proposal resulting from input by industry, including small businesses, refer to Unit XVIII.A.

Information relating to EPA's certification is provided upon request to the Chief Counsel for Advocacy of the Small Business Administration, and is included in the docket for this rulemaking. Any comments regarding the economic impacts that this proposed regulatory action may impose on small entities should be submitted to the Agency at the address listed in ADDRESSES.

C. Unfunded Mandates Reform Act

Under Title II of the Unfunded Mandates Reform Act of 1995 (UMRA) (Pub.L. 104-4), EPA has determined that this action does not contain a Federal mandate that may result in expenditures of $100 million or more for State, local, and tribal governments, in the aggregate, or the private sector in any one year. The costs associated with this action are described in the Executive Order 12866 section above. Therefore, this action is not subject to the requirements of sections 202 and 205 of the UMRA.

D. Consultation and Coordination with Indian Tribal Governments

Under Executive Order 13084, EPA may not issue a regulation that is not required by statute, that significantly or uniquely affects the communities of Indian tribal governments, and that imposes substantial direct compliance costs on those communities, unless the Federal government provides the funds necessary to pay the direct compliance costs incurred by the tribal governments. If the mandate is unfunded, EPA must provide to the Office of Management and Budget, in a separately identified section of the preamble to the rule, a description of the extent of EPA's prior consultation with representatives of affected tribal governments, a summary of the nature of their concerns, and a statement supporting the need to issue the regulation. In addition, Executive Order 13084 requires EPA to develop an effective process permitting elected and other representatives of Indian tribal governments "to provide meaningful and timely input in the development of regulatory policies on matters that significantly or uniquely affect their communities."

Tribal governments would not be subject to the requirements of today's proposal. In addition, for the most part, today's proposal implements requirements specifically set forth by the Congress in FIFRA without the exercise of any discretion by EPA. The remainder of today's proposal does not significantly or uniquely affect the communities of Indian tribal governments. Accordingly, the requirements of section 3(b) of Executive Order 13084 do not apply to this proposal.

E. Enhancing Intergovernmental Partnerships

Under Executive Order 12875, EPA may not issue a regulation that is not required by statute and that creates a mandate upon a State, local or tribal government, unless the Federal government provides the funds necessary to pay the direct compliance costs incurred by those governments. If the mandate is unfunded, EPA must provide to the Office of Management and Budget a description of the extent of EPA's prior consultation with representatives of affected State, local and tribal governments, the nature of their concerns, copies of any written communications from the governments, and a statement supporting the need to issue the regulation. In addition, Executive Order 12875 requires EPA to develop an effective process permitting elected officials and other representatives of State, local and tribal governments "to provide meaningful and timely input in the development of regulatory proposals containing significant unfunded mandates."

For the most part, today's proposal implements requirements specifically set forth by the Congress in FIFRA without the exercise of any discretion by EPA. The remainder of today's proposal would not impose any enforceable duties on State, local or tribal governments. Accordingly, the requirements of section 1(a) of Executive Order 12875 do not apply to this proposal.

F. Children's Health Protection

This proposed rule is not subject to E.O. 13045, entitled "Protection of Children from Environmental Health Risks and Safety Risks (62 FR 19885, April 23, 1997) because this action is not an economically significant regulatory action as defined by E.O. 12866 (see Unit XXI.A.). This proposed rule is procedural in nature and does not involve decisions on environmental health risks or safety risks that may disproportionately affect children.

G. National Technology Transfer and Advancement Act

Section 12(d) of the National Technology Transfer and Advancement Act of 1995 (NTTAA), 15 U.S.C. 272 note) directs EPA to use voluntary consensus standards in its regulatory activities unless to do so would be inconsistent with applicable law or impractical.
Voluntary consensus standards are technical standards (e.g., materials specifications,

test methods, sampling procedures, etc.) that are developed or adopted by voluntary consensus standards bodies. This proposed regulation does not involve technical standards that would require Agency consideration of voluntary consensus standards. EPA requests comment on this conclusion.

H. Environmental Justice

This proposed rule does not directly affect minority populations or low-income groups. Therefore, under Executive Order 12898, entitled *Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations* (59 FR 7629, February 16, 1994), the Agency has not considered environmental justice-related issues with regard to the potential impacts of this action on the environmental and health conditions in low-income and minority communities.

I. Paperwork Reduction Act

The information collection requirements contained in this proposed rule have been submitted to OMB under the Paperwork Reduction Act (PRA), 44 U.S.C. 3501 et seq, and in accordance with the procedures at 5 CFR 1320.11. An Information Collection Request (ICR) document has been prepared by EPA (EPA ICR No.[insert #]) and a copy may be obtained from Sandy Farmer, OPPE Regulatory Information Division; U.S. Environmental Protection Agency (2137); 401 M St., S.W.; Washington, DC 20460, by calling (202) 260-2740, or electronically by sending an e-mail message to "farmer.sandy@epamail.epa.gov." An electronic copy has also been posted with the **Federal Register** notice on EPA's homepage with other information related to this action. An Agency may not conduct or sponsor, and a person is not required to respond to a collection of information subject to OMB approval under the PRA unless it displays a currently valid OMB control number. The OMB control numbers for EPA's regulations, after initial publication in the **Federal Register**, are maintained in a list at 40 CFR part 9.

The annual public burden for this collection of information, which will be submitted for approval as an addendum to the existing ICR approved under OMB Control No. 2070-0060, is estimated to range from 1 hour to 10.4 hours per response, depending upon the activity. The cost is estimated to range from $71.00 to $755.00 per response, again depending on the particular response. The actual number of respondents and the frequency of response are not known because many of the responses are at the discretion of the respondent. However, based upon EPA estimates, the revisions in the proposed rule would increase the current burden by an estimated 6395 hours and $466,740.

Under the PRA, "burden" means the total time, effort, or financial resources expended by persons to generate, maintain, retain, or disclose or provide information to or for a Federal agency. For this collection it includes the time needed to review instructions; processing and maintaining information, and disclosing and providing information; search data sources; complete and review the collection of information;

and transmit or otherwise disclose the information.

Comments are requested on the Agency's need for this information, the accuracy of the provided burden estimates, and any suggested methods for minimizing respondent burden, including through the use of automated collection techniques. Send comments on the ICR to the EPA at the address provided above, with a copy to the Office of Information and Regulatory Affairs, Office of Management and Budget, 725 17th St., N.W., Washington, DC 20503, marked "Attention: Desk Officer for EPA." Please remember to include the ICR number in any correspondence. The final rule will respond to any comments on the information collection requirements contained in this proposal.

LIST OF SUBJECTS IN 40 CFR PARTS 152 AND 156

Administrative practice and procedure, Pesticides and pests, Reporting and recordkeeping requirements, Labeling, Occupational safety and health

Dated: _____

_____

Administrator.

Therefore, it is proposed that 40 CFR, Chapter I, Subchapter E be amended as follows:

1. In part 152:

a. The authority citation continues to read as follows:

Authority: 7 U.S.C. 136-136y.

b. Section 152.1 is revised to read as follows:

§ 152.1 Scope.

Part 152 sets out procedures, requirements and criteria for the registration of pesticide products under FIFRA sec. 3, and for associated regulatory activities affecting registration.

(a) Subparts A, B, C, E, F, G, I, and U apply to all products except antimicrobial products.

(b) Subparts A, B, E, F, G,, I, U and W apply to antimicrobial products.

c. Section 152.3 is amended by removing the paragraph designations for existing definitions, removing the definition of "pesticide," revising the definition for "active ingredient," and inserting alphabetically new definitions, to read as follows:

§ 152.3 Definitions.

* * * * *

"Active ingredient" means any substance (or group of structurally similar substances if specified by the Agency) in a pesticide product that will prevent, destroy, repel or mitigate any pest, or that functions as a plant regulator, desiccant, defoliant or nitrogen
stabilizer.

* * * * *

"Antimicrobial pesticide" means a pesticide product that:

(1) Is intended to have pesticide activity against microbiological pests, or to protect inanimate articles, substances, industrial processes or systems from deterioration, fouling, or contamination caused by bacterial, viral, fungal, protozoan, algal or slime pests; and

(2) In the intended use is exempt from or not subject to the requirement for a

tolerance under FFDCA sec. 408 or a food additive regulation under FFDCA sec. 409.

(3) The term does not include any of the following:

(I) A wood preservative or antifoulant paint that makes any non-antimicrobial pesticidal claim (such as insecticidal), regardless of whether it also makes an antimicrobial claim. A wood preservative that makes only an antimicrobial claim is an antimicrobial pesticide.

(ii) A fungicide for agricultural use. A fungicide is considered to be for agricultural use if it is intended to be applied to soil or to growing plants before harvest. A fungicide intended for post-harvest use is not considered to be for agricultural use. " Fungus," as defined in FIFRA, includes rust, smut, mildew, mold, yeast and bacteria.

(iii) A herbicide for aquatic use. A herbicide is considered to be for aquatic use if it is intended to be applied directly to natural or environmental bodies of water (such as lakes, ponds, or streams) or to terrestrial areas bordering environmental bodies of water for control of algae or weeds. A pesticide solely for control of algae in non-environmental waters (such as swimming pools or industrial water systems) is considered to be an antimicrobial pesticide and not an aquatic herbicide.

* * * * *

"Applicant" means a person applying for a new registration, or a registrant applying for an amended registration or submitting a notification.

"Application for registration" means an application for new or amended registration.

* * * * *

"Complete application" means an application for registration that contains all data, forms, and information required by EPA to be submitted with the application, and that will allow EPA to initiate review, notwithstanding that EPA may determine that additional information is required to approve the application. To be a complete application, each required item, and the application as a whole, must be determined by EPA to be complete, accurate, readable, and submitted in the format and number of copies required by the Agency.

* * * * *

"Fast-track application" means an application under FIFRA sec. 3(c)(3).

"FFDCA" means the Federal Food, Drug and Cosmetic Act, as amended (21 U.S.C 201 et seq.).

* * * * *

"Nitrogen stabilizer" means any substance or mixture of substances intended for preventing or hindering the process of nitrification, denitrification, ammonia volatilization or urease production through action upon soil bacteria, except that the term does not include:

(1) Dicyandiamide and ammonium thiosulfate; or

(2) Any substance or mixture of substances in commercial agronomic use before January 1, 1992, that was not registered before January 1, 1992, and for which the seller or distributor has made no specific claims of preventing or hindering the process ofnitrification, denitrification, ammonium volatilization or urease production after January 1, 1992.

"Registrant" means a person to whom a registration has been issued. In this part 152, if the term "applicant" and "registrant" would both apply, the term "applicant" is used.

d. By adding new § 152.6, to read as follows:

§ 152.6 Substances excluded from regulation by FIFRA.

Products and substances listed in this section are excluded from FIFRA regulation if they meet the specified conditions or criteria.

(a) Liquid chemical sterilants. A liquid chemical sterilant product is not a pesticide under FIFRA sec. 2(u) if it meets all of the following criteria. Excluded products are regulated by the Food and Drug Administration. Products excluded are those meeting all of the following criteria:

(1) Composition. The product must be in liquid form as sold or distributed. Pressurized gases or products in dry or semi-solid form are not excluded by this provision. Ethylene oxide products are not liquid products and are not exempt under this exclusion.

(2) Claims. The product must bear a sterilant claim, or a sterilant plus subordinate level disinfection claim. Products that bear antimicrobial claims solely at a level less than "sterilant" are not excluded and are jointly regulated by EPA and FDA. "Sterilant" is defined in § 156.441 of this chapter.

(3) Use site. The product must be intended and labeled only for use on "critical or semi-critical devices." A "critical device" is any device which is introduced directly into the human body, either into or in contact with the bloodstream or normally sterile areas of the body. A "semi-critical device" is any device which contacts intact mucous membranes but which does not ordinarily penetrate the blood barrier or otherwise enter normally sterile areas of the body. Liquid chemical sterilants that bear claims solely for non-critical medical devices are jointly regulated by EPA and FDA. Liquid chemical

sterilants bearing claims solely for use sites that are not medical devices, such as veterinary equipment, are not excluded and are regulated solely by EPA.

(b) Nitrogen stabilizers. A nitrogen stabilizer is excluded from regulation under FIFRA if it is a substance (or mixture of substances) meeting all of the following criteria:

(1) The substance prevents or hinders the process of nitrification, denitrification, ammonia volatilization, or urease production through action affecting soil bacteria and is distributed and sold solely for those purposes and no other pesticidal purposes.

(2) The substance was in "commercial agronomic use" in the United States before January 1, 1992. EPA considers a substance to be in commercial agronomic use if it is available for sale or distribution to users for direct agronomic benefit, as opposed to limited research, experimental or demonstration use.

(3) The substance was not registered under FIFRA before January 1, 1992.

(4) Since January 1, 1992, the distributor or seller has made no claim that the product prevents or hinders the process of nitrification, denitrification, ammonia volatilization or urease production. EPA considers any of the following claims (or their equivalents) to be a claim that the product prevents or hinders nitrification, denitrification, ammonia volatilization or urease production:

(i) Improves crop utilization of applied nitrogen.

(ii) Reduces leaching of applied nitrogen or reduces groundwater nitrogen contamination.

(iii) Prevents nitrogen loss.

(iv) Prolongs availability of nitrogen.

(v) Increases nitrogen uptake, availability, usage, or efficiency.

(5) A product will be consider to have met the criterion of paragraph (b)(4) that no nitrogen stabilization claim has been made if:

(i) The nitrogen stabilization claim, in whatever terms expressed, is made solely in compliance with a State requirement to include the claim in materials required to be submitted to a State legislative or regulatory authority, or in the labeling or other literature accompanying the product; and

(ii) The State requirement to include the claim was in effect both before the product bearing the claim was introduced into commercial agronomic use, and before the effective date of this rule.

(6) A product that meets all of the criteria of this paragraph with respect to one State is not thereby excluded from FIFRA regulation if distributed and sold in another State whose nitrogen stabilization statement requirement does not meet the requirements of paragraph (b)(5)(ii).

(c) Human drugs. Fungi, bacteria, viruses or other microorganisms in or on living man are not “pests” as defined in FIFRA sec. 2(t). Products intended and labeled for use against such organisms are human drugs and are subject to regulation by the Food and Drug Administration under the FFDCA.

(d) Animal drugs. Fungi, viruses, bacteria or other microorganisms on or in living animals are not "pests" under FIFRA sec. 2(t). Products intended and labeled for use against such organisms are animal drugs. A "new animal drug" as defined in section 201(w) of the FFDCA, or an animal drug that FDA has determined is not a "new animal drug" is not a pesticide under FIFRA sec. 2(u). Animal drugs are subject to regulation by the Food and Drug Administration under the FFDCA.

(e) Animal feeds. An animal feed containing a new animal drug is not a pesticide under FIFRA sec 2(u). Animal feeds containg new animal drugs are subject to regulation by the Food and Drug Administration under the FFDCA.

(f) Vitamin hormone products. A product consisting of a mixture of plant hormones, plant nutrients, inoculants, or soil amendments is not a "plant regulator" under FIFRA sec. 2(v), provided it meets the following criteria:

(1) The product, in the undiluted package concentration at which it is distributed or sold, meets the criteria of § 156.62 of this chapter for Toxicity Category III or IV; and

(2) The product is not intended for use on food crop sites, and is labeled accordingly.

§ 152.8 [Amended]

e. In § 152.8, by removing paragraphs (a), (b), (c)(2), (c)(3) and (c)(4), and redesignating paragraph (c)(1) as paragraph (a) and redesignating paragraph (d) as paragraph (b).

f. In § 152.20, by revising paragraph (b) to read as follows:

§ 152.20 Exemptions for pesticides regulated by another Federal agency.

* * * * *

(b) Non-liquid chemical sterilants. A non-liquid chemical sterilant, except ethylene oxide, that meets the criteria of § 152.6(a)(2) with respect to its claims and §

152.6(a)(3) with respect to its use sites is exempted from regulation under FIFRA.

§ 152.20 [Amended]

g. Section 152.25 is amended by removing paragraph (d) and redesignating the remaining paragraphs accordingly.

h. Section 152.44 is amended by removing paragraph (b)(3), redesignating paragraph (b)(4) as paragraph (b)(3), and adding new paragraph (c), to read as follows:

§ 152.44 Application for amended registration.

* * * * *

(c) A registrant may at any time submit identical minor labeling amendments affecting a number of products as a single application if no data are required for EPA to approve the amendment (for example, a change in the wording of a storage statement for designated residential use products). A consolidated application must clearly identify the labeling modification(s) to be made (which must be identical for all products included in the application), list the registration number of each product for which the modification is requested, and provide required supporting materials (for example, labeling) for each affected product.

i. By adding new subpart W, to read as follows:

SUBPART W--REGISTRATION OF ANTIMICROBIAL PRODUCTS

Sec.

§ 152.440 General.

(a) FIFRA sec. 3(h) requires EPA to establish by regulation procedures for the registration of certain antimicrobial pesticide products.

(b) In order to register, and lawfully distribute or sell, an antimicrobial product, a wood preservative or an antifouling paint covered by FIFRA sec. 3(h), an applicant must comply with each of the following:

(1) This subpart, which describes the requirements, procedures, conditions, and Agency review of applications for registration of antimicrobial products. This subpart W substitutes for subpart C of this part, which applies to all other products.

(2) Subparts A, B, E, F, G, I and U of this part 152. If any provision of subpart W conflicts with any provision of these subparts, subpart W applies instead.

(3) Part 158 of this chapter, which describes the data requirements for registration of antimicrobial products, wood preservatives, and antifouling paints.

(4) Part 156 of this chapter, which describes the labeling requirements applicable to all products. Subpart W of part 156 specifies efficacy performance standards and acceptable labeling claims for antimicrobial products bearing public health claims.

(5) Part 157 of this chapter, which establishes the criteria and requirements for the use of child-resistant packaging.

§ 152.441 Applicability.

(a) This subpart applies to an application for registration of a pesticide product that is any of the following:

(1) An antimicrobial pesticide, as defined by FIFRA sec. 2(mm) and § 152.3, including a wood preservative or antifouling paint product that makes only claims of antimicrobial pesticidal activity. All sections of this subpart apply to such products.

(2) Any product for which an antimicrobial claim is made, and which is used in such a manner that a new or modified clearance is required under FFDCA sec. 408 or 409. All sections of this subpart apply to such products, except § 152.457, *Review periods for applications*.

(b) This subpart does not apply to an application for registration of a pesticide product that is any of the following:

(1) A wood preservative that makes any non-antimicrobial pesticidal claim (for example, an insecticidal or fungicidal claim), regardless of whether an antimicrobial claim is also made for the product.

(2) An antifoulant product that makes any non-antimicrobial pesticidal claim, regardless of whether an antimicrobial claim is also made for the product.

§ 152.442 Definitions.

Terms used in this subpart have the same definitions as in the Act and subpart A of this part. For the purposes of this subpart, the following terms are defined:

"Clearance" means any of the following:

(1) A tolerance under FFDCA sec. 408(b).

(2) An exemption from the requirement of a tolerance under FFDCA sec. 408(c).

(3) A food additive regulation under FFDCA sec. 409.

(4) An approval of a medical device under FFDCA sec. 510(k).

"Complete application" means an application for registration that contains all data, forms, and information required by EPA to be submitted with the application, and

that will allow EPA to initiate review, notwithstanding that EPA may determine that additional information is required to approve the application. To be a complete application, each required item, and the application as a whole, must be determined by EPA to be complete, accurate, readable, and submitted in the format and number of copies required by the Agency.

"Major new use" means a new antimicrobial use of a registered active ingredient, as used in FIFRA sec. 3(h).

"Minor amendment" means an amendment to an antimicrobial registration that does not require the review of scientific data.

"Substantive amendment" means an amendment to an antimicrobial registration that requires scientific review of data.

§ 152.443 Who may apply.

(a) New registration. Any person may apply for new registration of an antimicrobial product. A person seeking a new registration for an antimicrobial product must submit an application for registration containing the information specified in § 152.450. An application for new registration must be approved by the Agency before the product may lawfully be distributed or sold, except as provided by § 152.30.

(b) Amended registration. (1) Any registrant may apply for amendment of his registration to modify the composition, labeling or packaging of the product. Except as provided by § 152.446, a registrant may modify the registration only by submitting an application for amended registration. The applicant must submit the information specified in § 152.450, as applicable to the change requested.

(2) Except as provided by paragraph (c), the registrant must submit a separate application for each registration.

(3) If an application for amendment is required, the application be approved by the Agency before the rpoduct, as modified, may lawfully be distributed or sold.

(c) Consolidation of amendments. A registrant may at any time submit identical minor labeling amendments affecting a number of products as a single application if no data are required for EPA to approve the amendment (for example, a change in the wording of a storage statement for designated household products). A consolidated application must clearly identify the labeling modification(s) to be made (which must be identical for all products), list the registration number of each product for which the modification is requested, and provide required supporting materials (for example, labeling) for each affected product.

(d) Alternatives to amendment. In its discretion, the Agency may:

(1) Waive the requirement for submission of an application for amended registration.

(2) Permit an applicant to modify a registration by notification or non-notification in accordance with § 152.446.

(e) Certification statement. In its discretion, the Agency may permit an applicant to certify to the Agency that the applicant has complied with an Agency directive or requirement with respect to any element of a new or amended registration. If the Agency determines that a requirement may be satisfied by an applicant certification, the Agency will provide, through a guidance document available to the general public, detailed instructions on a certification process. The guidance document will specify the content of a certification statement, any materials that must be submitted with the certification or maintained by the applicant, and the manner of submission of the certification.

§ 152.444 Alternate formulations.

(a) A product proposed for registration must have a single, defined composition of active and inert ingredients, except that EPA may approve a basic formulation and one or more alternate formulations under a single registration.

(b) An alternate formulation must meet the criteria listed in paragraph (b)(1) through (b)(4) of this section. The Agency may require the submission of data to determine whether the criteria have been met.

(1) The alternate formulation must contain, and have the same certified limits for, each active ingredient in the basic formulation.

(2) If the alternate formulation contains an inert ingredient or impurity of toxicological significance, the formulation must have the same upper certified limit for that substance as the basic formulation.

(3) The label text of the alternate formulation product must be identical to that of the basic formulation.

(4) The analytical methods required under § 158.180 of this chapter must be suitable for use on both the basic formulation and the alternate formulation.

(c) Notwithstanding the criteria in this section, the Agency may determine that an alternate formulation must be separately registered. If EPA makes this determination, the Agency will notify the applicant of its determination and its reasons.

Thereafter the application for an alternate formulation will be treated as an application for new registration.

§ 152.445 Types of antimicrobial applications.

The following types of applications are identified solely for purposes of this subpart, in order to establish review periods. Identification of application types in this section does not modify similar terms used elsewhere in EPA regulations. Application categories generally differ based upon factors related to the active ingredient status, the product formulation type, the uses proposed, and whether data are required with the application. An application may fall into only one category, as determined by EPA.

(a) **Application for registration of a food or feed use.** (1) Any application for registration that proposes a use that would require the establishment of a new or modified clearance under the FFDCA. Under the FFDCA, a clearance must be granted, either by EPA or by FDA, for uses that might result, directly or indirectly, in residues in raw or processed food or animal feed.

(2) The review periods in § 152.457 do not apply to applications covered by paragraph (a)(1) of this section. Such applications require significantly more data, require a longer review time, and are subject to formal approval by regulation under the FFDCA.

(b) **Application for new registration--**(1) **New active ingredient**. An application for registration of a new product containing any active ingredient that is not contained in a currently registered product.

(2) **Substantially similar product**. An application for new registration of a product that meets all of the criteria in this paragraph.

(i) **Formulation.** The product formulation contains the same active ingredients and is substantially similar in composition to a cited currently registered product.

(ii) **Uses**. The proposed uses are substantially similar to the uses on the label of the cited product. The proposed product may bear fewer uses than the cited product, but may not bear expanded uses or different uses or claims.

(iii) **Method of data support**. The application relies solely upon data from a substantially similar registration for support (with the exception of certain product chemistry data, which must be submitted for all new products) and does not require the submission of efficacy data.

(3) **Identical product**. An application for registration of a product that meets both of the criteria in this paragraph.

(i) **Formulation**. The formulation (including inert ingredients) is identical in composition to a cited currently registered formulation. Typically such a product either is a currently registered formulation that is being repackaged as a new product without separate production, or is a formulation of identical composition to another product that is being separately produced according to specifications provided by the registrant of the cited product.

(ii) **Uses and claims**. The proposed uses are identical to those on the cited product, with no deviation in use sites or directions for use. A product may have fewer uses or claims than on the cited product, but not different or expanded uses or claims.

(4) **New product with major new use.** An application for new registration that also proposes a "major new use," as described in paragraph (c)(1) of this section. Any application for a new registration that proposes only an additional or different use that is not a major new use will be considered to be a new registration described in paragraph (b)(5) of this section.

(5) **Other new product.** Any application for new registration that does not meet the criteria of paragraph (b)(1)-(4) of this section. These products usually require the submission of data. Examples of what would be included in this category are applications for registration of a product of any of the types listed below.

(i) The product is a formulation of different active ingredients than is contained in any currently registered product.

(ii) The product contains the same active ingredients, but is in a different physical form (liquid, powder) than any other registered product containing the same active ingredients, or is not substantially similar in composition to a cited currently registered product.

(iii) The product has any unregistered source of any active ingredient, regardless of the fact that the active ingredient is currently registered in another product. Use of an unregistered source of active ingredient requires review of supporting data for the unregistered ingredient.

(iv) The product has an additional use that is not currently registered for any substantially similar product.

(v) The product requires the submission of efficacy data because the

formulation is not identical to another product.

(c) **Amendments to registration**--(1) **Major new use**. An application for amended registration to add a major new use that is not currently registered for one or more of the active ingredients in the product. The major new use would generally be significantly different in the manner of use and exposure to humans or the environment from other registered use patterns for the active ingredient.

(2) **Substantive amendment**. An amendment that is not a major new use, and that requires scientific review of data. These include, but are not limited to, the following types of amendments:

(i) Any amendment that contains a data submission.

(ii) The addition of a use that has been approved for another registered product containing the same active ingredients, but which is not a substantially similar product as the registration for which the amendment is sought.

(iii) Except as permitted by § 152.446, *Notifications and non-notifications*, a change in precautionary or other hazard statements, use instructions, minor changes in ingredients that do not modify label statements, change in use concentrations, method of application, or pests.

(3) **Minor amendment**. An amendment to an existing registration which does not require scientific review of any type. In no case does an application for a minor amendment contain data for review. A minor amendment might include, but is not limited to, changes for which EPA must:

(i) Examine briefly or determine the applicability of previously submitted data (without scientific evaluation of such data).

(ii) Compare composition, characteristics or labeling with other products.

(iii) Evaluate the adequacy of the applicant's data citations or method of support.

(iv) Determine whether an adequate basis exists for a proposed label statement.

(v) Determine whether a proposed use is substantially similar to an approved use for a cited substantially similar product.

§ 152.446 Notifications and non-notifications.

(a) Changes permitted by notification--(1) Notifications permitted by statute. A registrant of an antimicrobial product may add relevant information on product efficacy, product composition, container composition or design, or other characteristics

that do not relate to pesticidal claims or activity. An example of a product efficacy claim that does not relate to pesticidal claims or activity would be a cleaning, deodorizing or polishing claim.

(2) Notifications permitted by EPA. In addition, EPA may determine that certain minor modifications to registration having no potential to cause unreasonable adverse effects to the environment may be accomplished by notification to the Agency, without requiring the registrant to obtain Agency approval. If EPA so determines, it will issue a notice to registrants describing the types of modifications permitted by notification.

(b) Procedure for notification. All notifications must be submitted in accordance with the procedures of this paragraph and any supplemental notice to registrants.

(1) Submission. A registrant must submit the notification to the Agency at least 60 days before distribution or sale of a product as modified.

(2) Substantiation. The registrant must retain, and submit to the Agency upon request, substantiating information or data supporting the proposed modification. These data need not be submitted with the notification unless specified in a notice issued in accordance with paragraph (a)(2) of this section. The substantiating information may be required, however, in accordance with paragraph (b)(4) of this section if the notification is disapproved.

(3) Agency decision. Within 30 days after receipt, the Agency will notify the registrant in writing if the notification is disapproved and state the reasons why it is unacceptable.

(4) Objection. A registrant may file an objection to a disapproval in writing not later than 30 days after receipt of the Agency's disapproval. If the basis for the disapproval is that substantiating information is needed, the registrant must submit such information as part of the objection. A decision by EPA after receipt and consideration of an objection is a final agency action.

(5) Distribution or sale. A registrant may not distribute or sell a product for which a modification by notification is proposed until he receives EPA notice of approval, or until 60 days after submission of the notification, whichever comes first. A registrant may not sell or distribute a product bearing a disapproved modification.

(c) Changes permitted without notification. EPA may determine that certain minor changes to registration having no potential to cause unreasonable adverse effects to the environment may be accomplished without notification to or approval by the Agency. If EPA so determines, it will issue a notice to registrants describing the types of changes permitted without notification (known as non-notifications). A registrant may distribute or sell a product changed as permitted by such notice without notification to or approval by the Agency.

(d) Effect of non-compliance. Notwithstanding any other provision of this section, if the Agency determines that a product has been modified through notification or without notification in a manner inconsistent with paragraphs (a) through (c) of this section or any notice issued thereunder, EPA may initiate regulatory or enforcement action, or both, without first providing the registrant with an opportunity to submit an application for amended registration.

§ 152.447 Consultation with EPA.

(a) Optional consultation. An applicant may consult the Agency at any time prior to submitting an application. Consultations should be by the most efficient and least time-consuming method available that satisfies the applicant's need. For minor questions or guidance, fax and e-mail are preferred, so that the Agency may respond both rapidly and in writing.

(b) Meetings. If a meeting is desired, applicants should contact the appropriate team leader or Branch Chief and provide a proposed agenda, list of likely attendees, and requested date(s). If EPA agrees that a meeting would be productive, EPA will schedule the meeting, honoring the applicant's requested times insofar as practicable, and will invite needed Agency personnel. EPA may choose not to meet with applicants if matters can be resolved by other means.

(c) Required consultation. An applicant must consult the Agency before submitting an application for registration if:

(1) The application is for a new chemical or major new use. It is strongly recommended that this consultation be a meeting or conference call with written confirmation of any agreements.

(2) The applicant wishes to develop data using different or modified protocols for required efficacy studies, or if no test method is specified. In some cases, EPA approval of alternate protocols and test standards is required. Consultation would typically consist of a written explanation of the modifications proposed or the proposed protocol, which EPA would approve in writing.

(d) Written determinations. An applicant may rely upon regulatory determinations only if in writing from EPA.

(e) Reliance on EPA determinations. EPA will not change the regulatory decisions contained in a written determination issued under paragraph (d) of this section unless:

(1) EPA concludes that its determination was in error.

(2) The applicant modifies the circumstances upon which the determination was based or EPA determines that the circumstances are other than described by the applicant.

(3) The applicant fails to submit the application in a timely manner, such that EPA's determination no longer comports with Agency regulations or policy; or

(4) EPA has information that raises concerns that an unreasonable adverse effect on the environment may result unless it changes its determination.

§ 152.450 Contents of application.

Each application for registration must include the data, information and forms listed in this section.

(a) Application for registration. The applicant must submit an application form provided by the Agency. The application form is required for all applications, both new and amended, as well as for notifications under § 152.446. To be complete:

(1) The applicable parts of the form must be properly and accurately filled in, according to the instructions provided with the form.

(2) The applicant must identify on the form which type of application the applicant believes is being submitted for purposes of review time computation. Types of applications are listed in § 152.445.

(3) If the application relies on an "identical" or "substantially similar" product, the applicant must provide the EPA Registration Number of the product claimed as identical or substantially similar.

(4) The form must be signed by an authorized representative of the applicant and must be dated.

(b) Authorization for agent. The applicant must submit a letter of authorization designating an agent residing in the United States if the applicant is located outside of the United States or if the applicant wishes to use an agent. To be complete, the authorization must:

(1) Be on the applicant's company letterhead;

(2) Provide identifying information for the agent, including name, address, and telephone numbers (fax and e-mail are requested if available);

(3) Affirm that the person designated is authorized to serve as agent with

respect to specified applications or registrations and provide a clear description of the products or applications covered and any limitations on the authorization; and

(4) Be signed (with name and title) by an authorized representative of the applicant and be dated.

(c) Summary of application. An application for registration must contain a publicly releasable summary of the application, including a list of the data submitted or cited in support of the application, together with a brief summary of the results of any studies submitted. This summary may be combined with that required for any other purpose.

(d) Statement of Formula. (1) The applicant must submit a Statement of Formula that identifies the composition of the product proposed for registration. A Statement of Formula is required for:

(i) Each application for new registration;

(ii) Each application for amended registration that proposes any change in the product composition or a change in other information on the previous Statement of Formula; and

(iii) Each notification under § 152.446 which affects the composition of the product.

(2) To be complete, the Statement of Formula must be accurately filled out with all required information, and must be signed by an authorized representative of the applicant.

(e) Labeling. (1) The applicant must submit the number of copies of draft labeling specified by the Agency. Generally four copies of draft labeling must be submitted. Draft labeling is required for:

(i) Each application for new registration.

(ii) Each application for amended registration, if the amendment proposes a label change or a labeling change is otherwise necessitated by the amendment (e.g., a change in composition affecting the labeling).

(iii) Each notification under § 152.446 that modifies any portion of the labeling.

(2) To be complete, the labeling submission must:

(i) Include both the product label and any supplemental labeling, brochures or other printed material that is intended to accompany the product in distribution or sale.

(ii) In the case of an amendment to existing labeling, be identical in wording to the last approved labeling, except for proposed changes (and any previously accepted notification), which must be marked.

(iii) Be suitable for photocopying. In general, highlighting does not photocopy; changes need to be marked or circled in black ink. Product packaging bearing the labeling is not acceptable for this purpose.

(f) Method of support documentation. The applicant must submit documentation of the method of support that will be used to satisfy each data requirement that applies to the application. Various forms provided by the Agency must be submitted to document the applicant's choices. This paragraph summarizes data support requirements. The applicant must comply with subpart E of this part, which contains detailed requirements and exceptions to the data support process.

(1) In general, the following choices for each data requirement are available:

(i) The applicant may submit the data. In all cases, an applicant may submit a study that satisfies a data requirement. Typically certain data must be submitted (product chemistry) and may not be cited. Refer to paragraph (g) of this section for information on data submission.

(ii) The applicant may cite the data with permission or offer to pay. If the data are exclusive use data, the applicant must have written permission from the data submitter. If the data are subject to compensation provisions, the applicant must have made appropriate offers to pay to each data submitter(s). Refer to paragraph (f)(2) of this section for the forms used to properly document citation of data.

(iii) The applicant may request in writing a waiver of the data requirement, together with a rationale for each waiver requested. A waiver request without a rationale is not complete.

(2) To be complete, the applicant who submits or cites data to satisfy any data requirement must submit, as applicable, one or more of the following:

(i) A Data Reference sheet (data matrix). This is a listing of all data requirements applicable to the product, identifying the means of satisfying each requirement, and must be submitted whenever an applicant submits his own data or uses the selective method of data support (see § 152.90). To be complete, each citation of data must include the Master Record Identification number, if known, or contain sufficient detail (title, date of submission, name and EPA identifying number of product) that EPA may clearly identify the item of data in its files.

(ii) A Formulator's Exemption form. This form is used when the applicant claims an exemption from certain data requirements because the applicant produces his product using a purchased registered source product. A single formulator's exemption

form may be used for all data requirements to which the exemption applies. The form must identify the registration number of each source product.

(iii) Certification with Respect to Citation of Data. This form is used to certify that the applicant has complied with all requirements pertaining to data submission and citation. The form must be submitted with each application for registration.

(g) Data and information. (1) The applicant must satisfy data requirements by submitting or properly citing data and information in support of the application, unless the applicant obtains a waiver of the data requirement, or unless EPA permits an alternate method of satisfying data requirements (such as certification). Data requirements are found in part 158 of this chapter.

(2) To be complete, the data submission must meet the following criteria:

(i) Final report of study. The submission must contain a final report of each study, including all information specified in Agency guidance (e.g., identity of substance tested).

(ii) Summary of results of data. The application must include a publicly releasable summary of the results of each study submitted. The results of all studies may be consolidated into a single summary.

(iii) Format. Each study individually, and the data submission as a whole, must conform to Agency requirements for formatting and presentation, as specified in § 158.32 of this chapter and Agency guidance.

(iv) Confidential business information (CBI). Each study must conform to Agency requirements in § 158.33 with respect to identification, marking and presentation of CBI.

(v) Certification of Good Laboratory Practice (GLP) compliance. Each study must include a certification in accordance with § 160.12 of this chapter.

(vi) Identification of studies demonstrating potential adverse effects. Each study that meets the criteria of § 158.34 of this chapter for potential adverse effects must be identified and the certification statement required by that section must be included. The studies to which this requirement applies are subchronic and chronic toxicity studies.

(h) Data or information pertaining to adverse effects. An applicant must submit any factual information regarding unreasonable adverse effects of this pesticide on man or the environment. The information that must be submitted is that which would be required to be reported under FIFRA sec. 6(a)(2) if the product were registered (see 40 CFR part 159). This requirement applies to each application for new registration. The requirement does not apply to an application for amended registration. To be

complete, submission of adverse effects information must be in accordance with 40 CFR part 159.

(i) Food use clearance. If the application proposes a use of the pesticide on food or feed crops, or if the intended use of the pesticide results or may be expected to result, directly or indirectly, in pesticide chemical residues in or on food or feed, the applicant must submit one of the following:

(1) A citation to each clearance that covers the proposed food or feed use(s).

(2) A petition under FFDCA sec. 408 requesting the establishment of a food clearance for each ingredient for which there is no current clearance. Requirements for pesticide petitions are contained in 40 CFR part 180. If a petition is required, an application for registration is not complete unless all requirements for the petition are satisfied.

(3) Evidence of acceptance of a petition for a food additive regulation by the FDA, if a food additive regulation is required. A copy of the notice of filing of the petition in the **Federal Register** is acceptable for this purpose.

(j) Documentation of pre-submission consultation. If a pre-submission consultation is required by § 152.447, the applicant must submit written documentation that the consultation took place, and a copy of any resulting regulatory decisions regarding the application or its review (for example, agreement as to the type of application being submitted, or specific data requirements imposed or waived).

(k) Data reviews conducted by other regulatory authorities. The applicant must state whether the data supporting the application have been, or are being, reviewed by State, Federal, or other national authorities. If so, the applicant must identify the reviewing authority and purpose of the review and must submit any available data reviews conducted by such regulatory authorities that are in the applicant's possession. The applicant is not required to obtain regulatory reviews for this purpose.

(l) Other clearances. If the applicant is required to obtain clearances or approvals from other Federal (not State) agencies before a product may be distributed and sold, or used as proposed on the label, the applicant must submit either:

(1) A copy of each such clearance or approval if already obtained; or

(2) A copy of a request to the appropriate agency for each such clearance or approval.

(m) Packaging. (1) Child-resistant packaging (CRP). If the product is required by Part 157 of this chapter to be distributed and sold only in CRP, or if the product will be sold in CRP, the applicant must submit a certification statement that the product meets the criteria for CRP in 40 CFR 157.32.

(2) In no case is actual product packaging to be submitted with an application for registration. If EPA needs to evaluate the actual product packaging, it will request submission.

(n) Product samples. In no case is a sample of the product to be submitted with an application. Product or ingredient samples may be required by the Agency for various purposes, but will be requested separately and must be submitted to the address in the request.

(o) Self-addressed notice for completeness determination. (1) An applicant may (but is not required to) provide a postcard (preferred) or form letter that EPA may use for notification of receipt of an application that EPA has preliminarily determined is complete.

(2) A postcard or form letter for this purpose must be addressed to the applicant at his address of record, stamped with sufficient U.S. postage, and provide a means (checkoff, space, box) for EPA to record the registration number or file symbol of the application, the fact that the application is complete, the date of EPA receipt, and the expected date for decision based upon the type of application.

(3) If a means of notifying the applicant is not provided, EPA will not otherwise notify an applicant in writing that the application is complete. EPA may, but is not required to, telephone or e-mail an applicant who does not provide written means of notification.

(p) Fees. If fees are required to be submitted for any application, or in conjunction with a petition for a clearance associated with an application, such fees must be submitted in accordance with Agency guidance. An application is not complete unless required fees have been submitted.

(q) Authorizations. (1) The applicant is requested, but not required, to provide authorization for EPA to share studies submitted by the applicant, or EPA's reviews of such studies, with other regulatory authorities, including Federal, State, or other national bodies that may regulate pesticides. Such authorization would apply only to the exchange of data or EPA reviews of data that might contain Confidential Business Information (CBI) or information protected under FIFRA sec. 10(g), unless the applicant provided a broader disclosure authorization.

(2) If the applicant chooses to authorize any degree of data/review sharing, he should include with his application, on company letterhead and signed by an authorized representative of the applicant, one of the following:

(i) A blanket authorization for EPA to exchange data or EPA data reviews pertaining to all of the applicant's products.

(ii) A specific authorization for EPA to exchange data or EPA data reviews pertaining to an ingredient(s) or product(s) designated in the authorization.

(iii) A specific authorization for EPA to exchange data or EPA data reviews pertaining to data submitted with the application.

(iv) Any other form of authorization, identifying the ingredients, products or data to which the authorization pertains and limitations upon the authorization.

(3) If an applicant chooses not to authorize EPA data/review sharing at the time of application, EPA may, in its discretion, disclose data or reviews in those circumstances where no authorization is needed, and seek consent for disclosure where needed on a case-by-case basis.

§ 152.451 How to submit applications.

(a) Applications must be submitted to the Agency by U.S. mail, courier service, or in person. EPA provides in guidance documents or upon request the appropriate address for each type of delivery. Applications may not be submitted electronically or by fax.

(b) EPA will not automatically provide evidence of receipt of an application. An applicant who wishes confirmation of delivery to EPA should use certified mail or courier services that provide confirmation.

§ 152.455 Action on applications.

(a) Incomplete application. EPA will screen each application for completeness, as specified in § 152.450. If EPA determines that the application is not complete, EPA will notify the applicant in writing of the deficiency(ies) in the application. EPA will not place into review, or compute review periods, for any application it finds incomplete.

(b) Preliminary determination of complete application. If EPA makes a preliminary determination that the application is complete, it will place the application into review. The appropriate review period in § 152.457 will be computed from the date of receipt by EPA of the last item that completes the application.

(c) EPA review of application. EPA will review each application for which a preliminary determination of completeness has been made. EPA will notify the applicant in writing of its decision on the application upon completion of all required reviews. EPA may, in its discretion, communicate with the applicant informally on the progress and interim results of the review. Such informal communications do not

constitute a decision on the application, and do not affect the review period.

(d) Decision on application. When all reviews are completed, EPA will take one of the following actions on the application:

(1) Approve the application. (i) EPA will approve an application for registration if it meets the criteria of § 152.112, 152.113 or 152.114, as applicable.

(ii) If EPA approves the application, EPA will issue a Notice of Registration and provide the applicant a copy of the stamped approved labeling, together with any labeling modifications that must be made. Before distributing or selling the pesticide product, the applicant must submit final printed labeling to the Agency, modified as specified by EPA in approving the registration and in the number of copies required by EPA. Thereafter,
the registrant may distribute and sell the product under the terms approved by EPA.

(iii) If EPA approves the application for a product on terms that differ from those requested by the applicant, the applicant may file a written objection and request that EPA reconsider the terms that are objectionable. An objection must be filed within 30 days of the date on which EPA approved the application, and must set out in detail the basis of the objection and the alternative terms of registration requested. The applicant may not distribute or sell the product until the objection is resolved. EPA will use its best efforts to respond within 45 days of receipt of a timely, written objection.

(2) Determine that the application remains incomplete. EPA may determine that, notwithstanding its preliminary determination of completeness, the application remains incomplete. If EPA so determines, it will notify the applicant of the deficiencies in the application. The applicant's resubmission will be treated in accordance with either paragraph (d)(2)(i) or (d)(2)(ii).

(i) Qualifying resubmission. EPA will treat a complete and timely response from the applicant as a "qualifying resubmission" subject to the review period in § 152.457(e), and will make a final decision on the application without recomputing a full second review period provided by § 152.457(c) or (d), if:

(A) The original application has a review period of ≤ 120 days;
(B) EPA determines, in its sole discretion, that the deficiency is less serious; and
(C) The deficiency is corrected within 30 days of receipt of EPA's notice to the applicant.

(ii) Non-qualifying resubmission. EPA will recompute a second full review period beginning on the date of receipt of the last item completing the application, and will make a final decision on the application within the review periods in § 152.457(c) or (d), as applicable, if:

(A) The original application has a review period of >120 days;
(B) EPA determines, in its sole discretion, that the deficiency is serious; or
(C) The applicant does not respond within 30 days.

(3) Determine that the applicant has not supplied all data or information required to determine the acceptability of the registration. EPA may determine that, despite its preliminary determination of completeness, the applicant has not supplied sufficient information to issue a registration decision. If EPA so determines, it will notify the applicant, identify the additional information or data needed, and require that the applicant submit, by a specified date, the information or data needed. As of the date of EPA's notification to the applicant, the review period will stop. The elapsed time between date of notification and receipt of response will not be counted in computing the date for a decision under § 152.457. Based upon the nature of the deficiencies, the time anticipated for the applicant to correct the deficiencies, and the additional time needed by EPA to review the material submitted in response to the notice of deficiency, EPA will specify in its notification one of two review period decisions:

(i) EPA may specify that the review period will resume as of the date of receipt of the applicant's complete and timely response; or

(ii) EPA may specify that the review period will resume after a specified period following receipt of the applicant's complete and timely response.

(4) Deny the application for failure to submit required information. If, after notification in accordance with paragraph (d)(3), the applicant does not respond, or does not provide all required data or information within the specified time, EPA may deny the application in accordance with the procedures of § 152.118. These procedures provide that EPA will issue a Notice of Intent to Deny (NOID) the application, stating the reasons and factual basis for denial, and permit the applicant 30 days to take corrective action. The Agency's issuance of a NOID would constitute the action required by FIFRA sec. 3(h) to notify an applicant of the Agency's decision, and the 30 days allowed for correction or other action would not be counted in the computation of the review period. Alternatively, EPA may determine that the application remains incomplete, in accordance with paragraph (d)(2) of this section. In either case, any subsequent submission will be treated as if it were an original application, and the review period will start over upon receipt of a complete application.

(5) Deny the application for failure to meet the registration standard. EPA may deny an application for registration if the Agency determines that, based upon review of a complete application and all data required by the Act, this part and part 158 of this chapter, the product does not meet the criteria of FIFRA sec. 3(c)(5) or (7), as specified in §§ 152.112, 152.113, or 152.114. If EPA proposes to deny an application on this basis, the Agency will follow the procedures of § 152.118. The Agency's

issuance of a NOID would constitute the action required by FIFRA sec. 3(h) to notify an applicant of the Agency's decision, and the 30 days allowed for correction or other action would not be counted in the computation of the review period.

§ 152.457 Review periods for applications.

EPA will complete review of, and make a decision on whether to approve, each application type listed in § 152.445 within the review periods given in this section. The statutory timeframes are based upon submission of a complete application. The process of submission is not complete until EPA has received the application. Accordingly, review periods are computed from the date that EPA receives the last item of an application that it determines thereafter is a complete application.

(a) **Applications involving food/feed uses.** The time frames in this section do not apply to applications involving food or feed uses that may require a clearance under the FFDCA. EPA will attempt to review such applications in a time commensurate with similar non-food actions, but because these applications may require significantly more data and more formal procedures for approval, EPA has not established any review periods for such applications.

(b) **Fast-track applications.** An application that qualifies as a fast-track application under FIFRA sec. 3(c)(3)(B)(i) will be reviewed within 90 days after receipt of a complete application.

(c) **Application for new registration.** Except as provided in paragraph (e) of this section, EPA will issue a decision on a complete application for new registration within the review period listed in the table below:

REVIEW PERIOD FOR APPLICATIONS FOR NEW REGISTRATION

Type of application	Calendar days for issuance of decision after receipt of a complete application
New active ingredient product	540
Identical or substantially similar product	90
Product bearing a major new use	270
Other new product	120

(d) **Application for amended registration.** Except as provided in paragraph (e) of this section, EPA will issue a decision on a complete application for amended registration within the review period given in the table below:

REVIEW PERIOD FOR APPLICATIONS FOR AMENDMENT

Type of amendment	Calendar days for issuance of decision after receipt of a complete application
Major new use amendment	270
Minor amendment	90
Substantive amendment	90 - 180

(e) Qualifying resubmission. In the case of a qualifying resubmission under § 152.455(d)(2)(i), EPA will issue a decision on an application of the following type within the review period given in the table below:

REVIEW PERIOD FOR QUALIFYING RESUBMISSIONS

Resubmission of an application for--	Calendar days for issuance of decision after receipt of a complete resubmission
Registration of an identical or substantially similar product	60
Registration of "other new product"	90
Minor amendment	60

(f) **Applicant recourse for failure to issue decision within review period**. If EPA has not notified the applicant that the application is approved or denied within the review period set out in this section, or within an alternative review period agreed to by EPA and the applicant, the applicant may seek judicial review under 5 U.S.C. 7.

§ 152.458 Duration of registration.

(a) Products not bearing public health claims. The registration of a product that bears no public health claim, as defined in § 156.443 of this chapter, will be

effective until EPA takes action to suspend or cancel the registration.

(b) Products bearing public health claims. The registration of a product bearing a public health claim, as defined in § 156.443 of this chapter, will expire five years after the date specified in paragraph (b)(1) or (b)(2) of this section, as applicable, unless the requirements of paragraph (b)(3) of this section have been met. At the end of each five-year period thereafter, the registration will expire unless the requirements of paragraph (b)(3) of this section have been met with respect to the most recent five-year period.

(1) New products. The five-year period for products first registered after the effective date of this rule begins on the date of registration. EPA will incorporate the five-year term of registration in the notice of registration.

(2) Existing products. The five-year period for products already registered as of the effective date of this rule begins on the earliest of the following dates:

(i) The date of EPA approval of the first amendment after the effective date of this rule. EPA will incorporate the five-year term of registration into the letter of approval.

(ii) The date of EPA approval of reregistration of the product under FIFRA sec. 4.
EPA will incorporate the five-year term of registration into the letter of reregistration.

(iii) A date certain approximately six months after the effective date of the rule.

(3) The registration will not expire if:

(i) Within one year before each expiration date of the registration, the registrant completes one or more chemical analyses of the product according to the analytical method submitted under § 158.180 of this chapter.

(ii) Within one year before each expiration date of the registration, the registrant completes efficacy testing for each public health claim on the label in accordance with the most current Agency guidelines.

(iii) No later than 90 days before each expiration of the registration, the registrant submits to the Office of Pesticide Programs at EPA a written certification, signed by an authorized representative of the registrant. The registrant must certify to each of the following:

(A) The registrant has conducted the required tests, identifying the tests that were conducted.

(B) Each test was conducted in accordance with the most current EPA guidelinjes for product composition testing and efficacy testing, and with applicable

Good Laboratory Practice standards of part 160 of this chapter.

(C) Based upon the product composition tests, the product composition continues to conform to the most recent Statement of Formula approved by EPA.

(D) Based upon the efficacy testing, the product meets applicable performance standards of part 156, subpart W, for each public health claim made.

(E) The test results are maintained with the registrant and will be submitted to EPA upon request.

(4) If the registration expires, the product will be deemed to be an unregistered product. EPA will permit the continued distribution and sale of existing stocks of the product by the registrant for 90 days after the expiration date, and by others for one y ear after the expiration date, unless the Administrator determines that a different time period is needed.

§ 152.459 Terms and conditions of registration.

(a) General conditions. A registration shall be subject to such terms and conditions as EPA may establish at the time of issuance, including, but not limited to, the terms and conditions in § 152.115. Such terms and conditions will be specified in the notice of registration or letter approving an amendment of registration.

(b) Submission of efficacy data for non-public health products. Efficacy data for non-public health products are not generally required to be submitted with an application for registration, but are required to be maintained by the registrant. Upon request by EPA, the registrant must submit the efficacy data required by Part 158 for a non-public health product. EPA will notify the registrant and allow 30 days from date of receipt for submission of the data.

2. In part 156:

a. The authority citation for part 156 continues to read as follows:

Authority: 7 U.S.C. 136 - 136y.

b. In § 156.10, by revising paragraph (a)(1)(vii) and removing paragraph (h), to read as follows:

§ 156.10 Labeling requirements

(a) * * *

(1) * * *

(vii) Hazard and precautionary statements as prescribed in subpart D of this part for human and for domestic animal hazards and subpart E of this part for environmental hazards.

* * * * *

c. By adding new subpart D, to read as follows:

Subpart D--HUMAN HAZARD AND PRECAUTIONARY STATEMENTS

Sec.

§ 156.60 General.

Each product is required to bear hazard and precautionary statements for humans and domestic animals (if applicable) as prescribed in this subpart. Hazard statements describe the type of hazard that may occur, while precautionary statements will either direct or inform the user of actions to take to avoid the hazard or mitigate its effects.

(a) Location of statements--(1) Front panel statements. The signal word, child hazard warning, and, in certain cases, the first aid statement are required to appear on the front panel of the label, and also in any supplemental labeling intended

to accompany the product in distribution or sale.

(2) Statements elsewhere on label. Hazard and precautionary statements not required on the front panel may appear on other panels of the label, and may be required also in supplemental labeling. These include, but are not limited to, the human hazard and precautionary statements, domestic animal statements if applicable, Notes to Physician, and physical or chemical hazard statements.

(b) Placement and prominence--(1) Front panel statements. All required front panel warning statements shall be grouped together on the label, and shall appear with sufficient prominence relative to other front panel text and graphic material to make them unlikely to be overlooked under customary conditions of purchase and use. The table below shows the minimum type size requirements for the front panel warning statements for various front panel sizes.

TYPE SIZES FOR FRONT PANEL WARNING STATEMENTS

SIZE OF LABEL FRONT PANEL (Square Inches)	POINT SIZE	
	SIGNAL WORD All Capital Letters	CHILD HAZARD WARNING
5 and under	6	6
Over 5 to 10	10	6
Over 10 to 15	12	8
Over 15 to 30	14	10
Over 30	18	12

(2) Other required statements. All other hazard and precautionary statements must be at least 6 point type.

§ 156.62 Toxicity Category.

This section establishes four Toxicity Categories for acute hazards of pesticide products, Category I being the highest toxicity category. Most human hazard, precautionary statements, and human personal protective equipment statements are based upon the Toxicity Category of the pesticide product as sold or distributed. In certain cases, statements based upon the Toxicity Category of the product as diluted for use are also permitted. A Toxicity Category is assigned for each of five types of acute exposure, as specified in the table below.

ACUTE TOXICITY CATEGORIES FOR PESTICIDE PRODUCTS

Hazard Indicators	I	II	III	IV
Oral LD_{50}	Up to and including 50 mg/kg	> 50 thru 500 mg/kg	> 500 thru 5,000 mg/kg	> 5,000 mg/kg
Dermal LD_{50}	Up to and including 200 mg/kg	> 200 thru 2000 mg/kg	> 2000 thru 20,000 mg/kg	> 20,000 mg/kg
Inhalation LC_{50}	Up to and including 0.2 mg/liter	> 0.2 thru 2 mg/liter	> 2 thru 20 mg/liter	> 20 mg/liter
Eye irritation	Corrosive; corneal opacity not reversible within 7 days	Corneal opacity reversible within 7 days; irritation persisting for 7 days	No corneal opacity; irritation reversible within 7 days	No irritation
Skin irritation	Corrosive	Severe irritation at 72 hours	Moderate irritation at 72 hours	Mild or slight irritation at 72 hours

§ 156.64 Signal word.

(a) Requirement. Except as provided in paragraph (a)(4), each pesticide product must bear on the front panel a signal word, reflecting the highest Toxicity Category (Category I is the highest toxicity category) to which the product is assigned by any of the five routes of exposure in § 156.62. The signal word must also appear together with the heading for the human precautionary statement section of the labeling (see § 156.70).

(1) Toxicity Category I. Any pesticide product meeting the criteria of Toxicity Category I for any route of exposure must bear on the front panel the signal word "DANGER." In addition, if the product is assigned to Toxicity Category I on the basis of its oral, inhalation or dermal toxicity (as distinct from skin and eye irritation), the word "Poison" must appear in red on a background of distinctly contrasting color, and the skull and crossbones symbol must appear in immediate proximity to the word "Poison."

(2) Toxicity Category II. Any pesticide product meeting the criteria of Toxicity Category II as the highest category by any route of exposure must bear on the front panel the signal word "WARNING."

(3) Toxicity Category III. Any pesticide product meeting the criteria of Toxicity Category III as the highest category by any route of exposure must bear on the front panel the signal word "CAUTION."

(4) Toxicity Category IV. A pesticide product meeting the criteria of Toxicity Category IV by all routes of exposure is not required to bear a signal word. If a signal word is used, it must be “CAUTION.”

(b) Use of signal words. In no case may a product:

(1) Bear a signal word reflecting a higher Toxicity Category than indicated by the route of exposure of highest toxicity, unless the Agency determines that such labeling is necessary to prevent unreasonable adverse effects on man or the environment;

(2) Bear a signal word reflecting a lesser Toxicity Category associated with a diluted product. Although precautionary statements for use dilutions may be included on label, the signal word must reflect the toxicity of the product as distributed or sold; or

(3) Bear different signal words on different parts of the label.

§ 156.66 Child hazard warning.

(a) Each pesticide product must bear on the front panel of the label the statement "Keep Out of Reach of Children." The statement must appear on a separate line in close proximity to the signal word, if required. The statement is required on Toxicity Category IV products that do not otherwise require a signal word .

(b) EPA may waive the requirement, or require an alternative child hazard warning, if:

(1) The applicant can demonstrate that the likelihood of exposure of children to the pesticide during distribution, marketing, storage or use is remote (for example, an industrial use product); or

(2) The pesticide is approved for use on children (for example, an insect repellent).

(c) EPA may approve an alternative child hazard warning that more appropriately reflects the nature of the pesticide product to which children may be exposed (for example, an impregnated pet collar). In this case, EPA may also approve placement on other than the front panel.

§ 156.68 First aid statement.

(a) Product as sold and distributed. Each product must bear a first aid statement if the product has systemic effects in Category I, II, or III, or skin or eye irritation effects in Category I or II. First aid statements are based upon the Toxicity Category by each route of exposure for the product.

(b) Product as diluted for use. If the product labeling bears directions for dilution with water prior to use, the label may also include a statement describing how the first aid measures may be modified for the diluted product. Such a statement must reflect the Toxicity Category(ies) of the diluted product, based upon data for the route of

exposure (or calculations if appropriate). If the labeling provides for a range of use dilutions, only that use dilution representing the highest concentration allowed by labeling may be used as the basis for a statement pertaining to the diluted product. The statement for a diluted product may not substitute for the statement for the concentrate, but augments the information provided for the concentrate.

(c) Heading. The heading of the statement must be "First Aid."

(d) Location of first aid statement. The first aid statement must appear on the front panel of the label of all products assigned to Toxicity Category I by any route of exposure. Upon review, the Agency may permit reasonable variations in the placement of the first aid statement if a reference such as "See first aid statement on back panel" appears on the front panel. The first aid statement for products assigned to Toxicity Categories II or III may appear on any panel of the label.

§ 156.70 Precautionary statements for human hazards.

(a) Requirement. Human hazard and precautionary statements as required must appear together on the label or labeling under the general heading "Precautionary Statements" and under appropriate subheadings similar to "Humans and domestic animals," "Environmental hazards" (see subpart E of this part) and "Physical or chemical hazards." The phrase "and domestic animals" may be omitted from the heading if domestic animals will not be exposed to the product.

(b) Content of statements. When data or other information show that an acute hazard may exist to humans or domestic animals, the label must bear precautionary statements describing the particular hazard, the route(s) of exposure and the precautions to be taken to avoid accident, injury or toxic effect or to mitigate the effect. The precautionary paragraph must be immediately preceded by the appropriate signal word.

(c) Typical precautionary statements. The table below presents typical hazard and precautionary statements. Specific statements pertaining to the hazards of the product and its uses must be approved by the Agency. With Agency approval, statements may be augmented to reflect the hazards and precautions associated with the product as diluted for use. Refer to § 156.68(b) for requirements for use dilution statements.

TYPICAL HUMAN HAZARD AND PRECAUTIONARY STATEMENTS

Toxicity Category	Systemic Effects (Oral, Dermal, Inhalation Toxicity)	Irritation Effects (Skin and Eye)	Sensitizer (There are no categories of sensitization.)

I	Fatal (poisonous) if swallowed [inhaled or absorbed through skin]. Do not breathe vapor [dust or spray mist]. Do not get in eyes, on skin, or on clothing. [Front panel first aid statement required.]	Corrosive, causes eye and skin damage [or skin irritation]. Do not get in eyes on skin, or on clothing. Wear goggles or face shield and rubber gloves when handling. Harmful or fatal if swallowed. [Front panel first aid statement required.]	If product is a sensitizer: Prolonged or frequently repeated skin contact may cause allergic reactions in some individuals.
II	May be fatal if swallowed, [inhaled or absorbed through the skin]. Do not breathe vapors [dust or spray mist]. Do not get in eyes, on skin, or on clothing. [Appropriate first aid statement required.]	Causes eye [and skin] irritation. Do not get in eyes, on skin, or on clothing. Harmful if swallowed. [Appropriate first aid statement required.]	
III	Harmful if swallowed [inhaled or absorbed through the skin]. Avoid breathing vapors [dust or spray mist]. Avoid contact with skin [eyes or clothing]. [Appropriate first aid statement required.]	Avoid contact with skin, eyes or clothing. In case of contact immediately flush eyes or skin with plenty of water. Get medical attention if irritation persists.	
IV	No precautionary statements required	No precautionary statements required.	

§ 156.78 Precautionary statements for physical or chemical hazards.

(a) Requirement. Warning statements on the flammability or explosive characteristics of the pesticide product are required if a product meets the criteria in this section. Warning statements pertaining to other physical/chemical hazards (e.g., oxidizing potential, conductivity, chemical reactions leading to production of toxic substances) may be required on a case-by-case basis.

(b) Pressurized products. The table below sets out the required flammability label statements for pressurized products.

FLAMMABILITY STATEMENTS FOR PRESSURIZED PRODUCTS

Flash point/flame extension of product	Required labeling statement
--Flash point at or below 20° F **OR** --Flashback at any valve opening	Extremely flammable. Contents under pressure. Keep away from fire, sparks, and heated surfaces. Do not puncture or incinerate container. Exposure to temperatures above 130° F may cause bursting.
--Flash point > 20° F to 80° F **OR** --Flame extension more than 18 in. long at a distance of 6 in from the flame	Flammable. Contents under pressure. Keep away from heat, sparks and open flame. Do not puncture or incinerate container. Exposure to temperatures above 130° F may cause bursting.
All other pressurized products	Contents under pressure. Do not use or store near heat or open flame. Do not puncture or incinerate container. Exposure to temperatures above 130° F may cause bursting.

(c) Non-pressurized products. The table below sets out the required flammability label statements for non-pressurized products.

FLAMMABILITY STATEMENT FOR NON-PRESSURIZED PRODUCTS

Flash point	Required labeling statement
At or below 20° F	Extremely flammable. Keep away from fire, sparks and heated surfaces.
Greater than 20° F to 80° F	Flammable. Keep away from heat and open flame.
Greater than 80° F to 150° F	Combustible. Do not use or store near heat or open flame.

(d) Total release fogger products. (1) A "total release fogger" is defined as a pesticide product in a pressurized container designed to automatically release the total contents in one operation, for the purpose of creating a permeating fog within a confined space to deliver the pesticide throughout the space.

(2) If a pesticide product is at total release fogger containing a propellant with a flash point at or below 20° F, then the following special instructions must be added to the "Physical and Chemical Hazards" warning statement, in addition to any flammability statement required by paragraph (b) of this section:

This product contains a highly flammable ingredient. It may cause a fire or explosion if not used properly. Follow the Directions for Use on this label very carefully.

(3) A graphic symbol depicting fire, such as illustrated in this paragraph, or an equivalent symbol, must be displayed along with the required language adjoining the "Physical and Chemical Hazards" warning statement. The graphic symbol must be no smaller than twice the size of the first character of the human hazard signal word.

[Insert graphic of flammability symbol]

d. By adding new subpart E, to read as follows:

Subpart E--ENVIRONMENTAL HAZARD AND PRECAUTIONARY STATEMENTS

Sec.
156.80 General.
156.85 Non-target organisms.

§ 156.80 General.

(a) Requirement. Each product is required to bear hazard and precautionary statements for environmental hazards, including hazards to non-target organisms, as prescribed in this subpart. Hazard statements describe the type of hazard that may be present, while precautionary statements direct or inform the user of actions to take to avoid the hazard or mitigate its effects.

(b) Location of statements. Environmental hazard and precautionary statements may appear on any panel of the label and may be required also in supplemental labeling. The environmental hazard statements must appear together under the heading "Environmental hazards." Typically the statements are grouped as a sub-category within the "Precautionary Statements" section of the labeling.

(c) Type size. All environmental hazard and precautionary statements must be at least 6 point type.

§ 156.85 Non-target organisms.

(a) Requirement. Where a hazard exists to non-target organisms, EPA may require precautionary statements of the nature of the hazard and the appropriate precautions to avoid potential accident, injury or damage.

(b) Examples. The statements in this paragraph illustrate the types of hazard statements that EPA may require and the circumstances under which they are typically required. These statements are not comprehensive; other statements may be required

if more appropriate to the formulation or use.

(1) If a pesticide intended for outdoor use contains an active ingredient with a mammalian acute oral LD_{50} of 100 mg/kg or less, the statement, "This pesticide is toxic to wildlife" is required.

(2) If a pesticide intended for outdoor use contains an active ingredient with a fish acute LC_{50} of 1 ppm or less, the statement, "This pesticide is toxic to fish " is required.

(3) If a pesticide intended for outdoor use contains an active ingredient with an avian acute oral LD_{50} of 100 mg/kg or less, or a subacute dietary LC_{50} of 500 ppm or less, the statement, "This pesticide is toxic to wildlife" is required.

(4) If either accident history or field studies demonstrate that the use of the pesticide may result in fatality to birds, fish or mammals, the statement, "This pesticide is extremely toxic to wildlife (fish)" is required.

(5) If a product is intended for or involves foliar application to agricultural crops, forests or shade trees, or mosquito abatement treatments, and contains a pesticide toxic to pollinating insects, the label must bear appropriate label cautions.

(6) If a product is intended for outdoor use other than aquatic applications, the label must bear the caution, "Keep out of lakes, ponds or streams. Do not contaminate water by cleaning of equipment or disposal of wastes."

e. By adding new subpart W, to read as follows:

SUBPART W -- PUBLIC HEALTH CLAIMS FOR ANTIMICROBIAL PRODUCTS

Sec.

Authority: 7 U.S.C. 136-136y.

§ 156.440 Scope and applicability.

(a) Scope--(1) Performance standards. This subpart establishes performance standards for antimicrobial public health claims. The performance standards are based upon required efficacy testing for antimicrobial products specified in part 158 of this chapter. Test methods and standards, evaluation procedures and reporting standards referred to in this subpart are contained in the Pesticide Assessment Guidelines, Subdivision G. This subpart does not cover performance standards for non-public health claims.

(2) Acceptable public health claims. This subpart describes public health claims that may be made on antimicrobial product labeling based upon efficacy performance standards. This subpart also establishes limitations on the use of certain claims, as well as specific antimicrobial claims that are not acceptable on product labeling. An antimicrobial public health product that does not meet the performance standard in this subpart for a public health claim may not bear that claim.

(3) Use directions. This subpart describes certain use directions associated with public health claims, which are necessary to ensure that the product will achieve the level of antimicrobial performance claimed. This subpart does not set out use

directions for non-public health antimicrobial products, nor does it describe comprehensively the use directions for public health products or claims, which are specific to the use sites and patterns. Additional detailed guidance on use directions for antimicrobial products is provided in the Pesticide Assessment Guidelines, Subdivision H.

(b) Applicability. (1) This subpart applies to any antimicrobial product that is subject to the provisions of part 152, subpart W of this chapter, and that makes a public health claim.

(2) This subpart applies to end use antimicrobial products. This subpart does not apply to manufacturing use products.

§ 156.441 Definitions.

Terms defined in FIFRA and part 152 of this chapter are used with the same definitions as given therein. In addition, the following terms are defined for the purposes of this subpart:

"Disinfectant" means a substance that destroys or eliminates a specific species of infectious or other public health microorganism, but not necessarily bacterial spores, in the inanimate environment.

"Equivalent," when used with respect to a test protocol or method, means a test protocol or method, validated by multiple laboratory studies and approved by EPA, that accomplishes the purposes intended by the cited Guidelines test protocols, and that is expected to provide data of equal quality and completeness as data derived from testing according to an EPA Guideline protocol.

"Fungicide" means a substance that destroys fungi (including yeasts) and fungal spores pathogenic to man or other animals in the inanimate environment.

"Guidelines" means the Pesticide Assessment Guidelines, Subdivision G - Product Performance Test Guidelines, or the Harmonized OPPTS Test Guidelines, which are an updated, reformatted compilation of guidelines used for both pesticide and other chemical testing.

"Microbiological water purifier" means any unit, water treatment product or system that removes, kills or inactivates all types of disease-causing microorganisms from the water, including bacteria, viruses and protozoan cysts, so as to render the treated water safe for drinking.

"Public health product" means an antimicrobial product that bears a public health claim as defined in § 156.443. A public health product is also a “public health pesticide” as defined in FIFRA sec. 2(nn).

"Sanitizer" means a substance that reduces the bacterial population in the inanimate environment by significant numbers, but does not destroy or eliminate all bacteria or other microorganisms.

"Sterilant" means a substance that destroys or eliminates all forms of microbial life in the inanimate environment, including all forms of vegetative bacteria, bacterial spores, fungi, fungal spores, and viruses. For purposes of this subpart, "sporicide" and "sterilant" are synonymous.

"Tuberculocide" means a substance that destroys or inactivates tubercle bacilli in the inanimate environment.

"Virucide" means a substance that destroys or inactivates viruses in the inanimate environment.

§ 156.442 Use of terms and statements on labeling.

When this subpart authorizes the use of a term on product labeling, other grammatical variants, phrases and statements having the same or equivalent connotation are also authorized, unless EPA, on a case-by-case basis, prohibits their use. For example, authorization to use the term "sterilant" also means that "sterilizer," "sterilization" and similar terms may be used. EPA approves the content of each label, and may, in its discretion, limit the use of certain terms, phrases or statements.

§ 156.443 Public health claims.

EPA will consider a product to make a public health claim if any of the following applies:

(a) A claim is made for control of specific microorganisms or classes of microorganisms that are directly or indirectly infectious or pathogenic to man (or both man and animals). Examples of specific microorganisms include *Mycobacterium tuberculosis*, *Pseudomonas aeruginosa*, *E. coli*, *HIV*, *Streptococcus*, and *Staphylococcus aureus*. Claims for control of microorganisms infectious or pathogenic only to animals (such as canine distemper virus or hog cholera virus) are not considered public health claims.

(b) A claim is made for the product as a sterilant, disinfectant, virucide, or sanitizer, regardless of the site of use of the product, and regardless of whether specific microorganisms are identified.

(c) A claim is made for the product as a fungicide against fungi infectious or pathogenic to man, or the product does not clearly indicate it is intended for use only against non-public health fungi.

(d) A claim is made for the product as a microbiological water purifier (see § 156.457).

(e) A non-specific claim is made that the product will beneficially impact or affect public health at the site of use or in the environment in which applied (such as a “ sanitary” claim), and:

(1) The product contains one or more ingredients that, under the criteria in 40 CFR 153.125(a), is considered an active ingredient with respect to a public health microorganism and there is no other functional purpose for the ingredient in the product; or

(2) The product is similar in composition to registered products that make explicit antimicrobial public health claims.

§ 156.444 Unacceptable statements and claims.

No pesticide or device, including an antimicrobial pesticide product, may bear false or misleading claims or statements (including the name of the product). Claims or statements of the type identified in this section are deemed to be false or misleading and are not acceptable on product labeling. Effective on **[date certain - 1 year]**, EPA will regard an antimicrobial product bearing a statement, claim, or product name that is unacceptable under this section to be misbranded under FIFRA sec. 2(q).

(a) Statements or claims that suggest or imply greater effectiveness because of composition, e.g., "hospital" strength or grade, "industrial strength," "extra strength."

(b) Statements or claims that suggest or imply that the product can or will prevent or control disease or offer health protection. Claims such as "prevents infection," "controls infection" or "prevents cross-infection" or that the product will control or mitigate any disease (such as Legionnaire's disease), infection, or pathological condition constitute drug claims regulated by the Food and Drug Administration. A claim that the product "controls cross-contamination from treated surfaces," or "kills [name of specific organism] in the inanimate environment" is acceptable.

(c) Statements or claims that are overly broad, non-specific, ambiguous or exaggerated.

(1) The terms "microbicide" and "microbistat" are not acceptable on a public health product. If used on a non-public health product, the claim must be qualified to indicate that the product does not provide public health protection.

(2) The term "biocide" is unacceptable on a public health product because it implies that the product can kill all living organisms, including plants and animals. If

used on a non-public health product, the term must be qualified by directions for use or other statements that make clear the types of organisms to be controlled.

(3) The term "antibacterial" or "germicidal" is not acceptable on a non-public health product. If used on a public health product, the labeling must identify the specific organisms to be controlled.

(4) The term “antimicrobial” is not acceptable on a non-public health product, unless clearly and properly qualified to indicate that the product does not provide public health protection. “Clearly and properly qualified” means, at a minimum, that:

(i) The term “antimicrobial” is clearly associated with, and in close proximity to, its qualifying statement on the labeling. It is always unacceptable for the term “ antimicrobial” to appear on a different label panel from its qualifying statement.

(ii) The term “antimicrobial” is not highlighted or given prominence over the qualifying statement by means of placement or presentation (e.g., type size, style, color or contrast).

(iii) The term “antimicrobial” is not part of the product name.

(5) The prefix "steri-" implies sterilant activity, and may not be used in the product name or on a product that is not a sterilant.

(6) Statements or claims implying indefinite or all-encompassing antimicrobial protection against bacteria, fungi or algae ("germ-free", “mildew-proof”, “algae-free”) are not acceptable.

(d) Claims or statements that differ from or do not accurately reflect the results demonstrated by testing.

(1) Product names or other claims or statements expressing or implying a higher level of antimicrobial activity than that demonstrated by testing, even if qualified (for example, "sterisure bacteriostat"). The labeling must unambiguously identify the level of antimicrobial activity (disinfectant, sanitizer, etc).

(2) Claims or statements that are inconsistent with conditions of efficacy established by testing (e.g., a claim of efficacy within 30 seconds, when testing and use directions require 2 minutes contact time for efficacy.)

(e) Statements or claims of efficacy based on unsubstantiated, improbable or irrelevant site/pest relationships. For example, a claim of efficacy against a pest not likely to occur on the site (e.g., athlete's foot fungi in toilet bowls) is misleading.

(f) A statement or claim of presumptive or screening efficacy, even if qualified, is

not acceptable on an end use product. Presumptive efficacy testing is intended to demonstrate that an active ingredient is capable of antimicrobial efficacy, but such testing is not conducted under specific conditions of use. An end use product must be tested for, demonstrate, and be labeled for a specific level of antimicrobial efficacy against identified organisms under conditions of use likely to be encountered.

(1) Legionnaire's disease claims in cooling tower water are not acceptable. Express or implied claims that a product will prevent growth or spread of Legionnaire's Disease bacteria (LDB) are unacceptable. Product labeling may provide accurate information concerning current knowledge and recommendations of the Public Health Service, or laboratory test data showing presumptive effectiveness of the product against pure cultures of LDB. Such information must be qualified by statements to the effect that findings are presumptive, and that there is no evidence that chemical treatment will control LDB growth under actual use conditions, reduce transmission of LDB or prevent Legionnaire's Disease.

(2) No statement of phenol coefficient may appear on a public health end use product. The phenol coefficient is a calculated comparison of presumptive efficacy.

(g) Certain symbols, icons, or graphics are unacceptable.

(1) The caduceus symbol is not acceptable because it is a medical symbol that implies endorsement by the medical profession or broad medical significance or health protection that is not acceptable in accordance with paragraph (b) of this section.

(2) The name and symbol of the Red Cross are not permitted on any product.

§ 156.445 Sterilant claim on hard surfaces.

(a) Performance standard. (1) When tested in accordance with the test methods and standards in § 810.2100(b)(1) and (2) of the guidelines or its equivalent, the product kills all test spores on all carriers with no failures; and

(2) When tested by a laboratory independent of the registrant in accordance with the test methods and standards in § 810.2100(b)(4), the product kills all test spores on all carriers with no failures.

(b) Acceptable claim. (1) A product that meets the performance standard in paragraph (a) may bear "sterilant" claims or variants of these.

(2) Since a sterilizer by definition destroys or eliminates all forms of microbial life, a sterilant product may bear claims of any lesser efficacy levels, such as disinfectant, bactericidal, tuberculocidal, fungicidal, virucidal or sanitizer. Separate directions for use must be provided for each lesser level of antimicrobial activity.

(c) Unacceptable claims. (1) Liquid chemical germicides may not make sterilant claims for critical or semi-critical medical devices. Claims for liquid chemical germicides are limited to pre-cleaning critical or semi-critical medical devices prior to sterilization.

(2) "One-step" claims are not allowed for sterilants. The label must require pre-cleaning of surfaces prior to sterilization.

§ 156.446 Disinfectant claim on hard surfaces.

(a) Performance standard. (1) When tested in accordance with the test methods and standards in § 810.2100(c),(d), or (e) of the guidelines or its equivalent, the product kills the test microorganisms on 59 out of each set of 60 carriers/slides. Although the performance standard is the same for all disinfectant claims, the test standards and test microorganisms define the level of disinfectant claim that may be made on product labeling.

(2) An applicant who wishes to make disinfectant claims for additional microorganisms not designated in the test methods and standards may do so based upon efficacy tests conducted with those additional microorganisms. When tested in accordance with the test methods and standards in § 810.2100(k) or its equivalent, for each organism the product must kill all test organisms on 10 carriers for each of two samples representing two different batches.

(b) Acceptable limited disinfectant claim--(1) Products containing pine oil. A product containing pine oil (as sole active ingredient or in combination with other ingredients) and that meets the performance standard in paragraph (a) when tested using the test standards in § 810.2100(c) and the test microorganism *Salmonella cholerasuis* may bear only a claim as a "limited disinfectant against bacteria of intestinal origin."

(2) All other products. A product that meets the performance standard in paragraph (a) of this section for only one major group of microorganisms (Gram negative or Gram positive bacteria) when tested using the test standards of § 810.2100(c) may bear only a claim as a "limited disinfectant." The product labeling must identify the specific organisms against which the product is effective.

(c) Acceptable general or broad spectrum disinfectant claim. A product that meets the performance standard in paragraph (a) of this section for both Gram negative and Gram positive bacteria when tested using the test standards of § 810.2100(d) may bear a claim as a "general or broad spectrum disinfectant," and may also bear a claim as a "hard food contact surface disinfectant." The product labeling must identify the specific organisms against which the product is effective.

(d) Acceptable hospital or medical disinfectant claim. A product that meets the performance standard in paragraph (a) of this section when tested in accordance with the test standard in § 810.2100(e) may bear a claim as a "hospital or medical environment disinfectant," and may also bear a claim as a "hard food contact surface disinfectant." The product labeling must identify the specific organisms against which the product is effective.

(e) Towelette disinfectant claims--(1) Single use towelettes. A single use towelette may bear a claim as a "single use towelette for the disinfection of hard surfaces" if, when tested by methods and standards approved by EPA [810.2100(i)(1)(i) or its equivalent], it meets the performance standard in § 810.2100(i)(3)(i).

(2) Multiple use towelettes. A multiple use towelette may bear a claim as a "multiple use towelette for the disinfection of hard surfaces" if, when tested by the methods and standards approved by EPA [810.2100(i)(1)(ii) or its equivalent], it meets the performance standard in § 810.2100(i)(3)(ii).

(f) Unacceptable claims. (1) A product that functions by fogging may not bear claims of disinfection for duct systems, air, or room surfaces.

(2) Products with circulate-in-place (CIP) applications may not bear claims of disinfection because CIP application has not been shown to be effective in disinfecting duct systems, air or room surfaces. CIP products may, however, bear claims of sanitization if they meet the performance standard of § 156.451.

§ 156.447 Fungicidal claim on hard surfaces.

(a) Performance standard. (1) The product meets the performance standard of § 810.2100(d) as a broad spectrum disinfectant; and

(2) When tested in accordance with the test methods and standards in § 810.2100(f) of the guidelines or its equivalent, the product kills all fungal spores.

(b) Acceptable claim. A product that meets the performance standard in paragraph (a) of this section may bear a claim of effectiveness as a "fungicide" or against "pathogenic fungi" on appropriate surfaces or sites.

§ 156.448 Virucidal claim on hard surfaces.

(a) Performance standard. (1) The product meets the performance standard of § 810.2100(d) as a broad spectrum disinfectant; and

(2) When tested in accordance with the test methods and standards in § 810.2100(g) of the guidelines or its equivalent, the product:

(i) Inactivates virus at all dilutions when cytotoxicity is not observed in the assay system, or at all dilutions above the cytotoxic level when cytotoxicity is observed; and

(ii) Achieves at least a 99.9% (3-log) reduction in viral titer in all samples when cytotoxicity is present.

(b) Acceptable claim--(1) Combination disinfectant/virucidal products. A disinfectant product that also meets the performance standard in paragraph (a) of this section may also bear a claim of effectiveness as a "virucide" or as "virucidal." The product labeling must identify the specific viruses against which the product is effective.

(2) Virucide only products. A product that meets the performance standard in paragraph (a) of this section, but is not a disinfectant, may bear only a limited claim of effectiveness against viruses specifically tested against, and must bear a disclaimer that the product is not a disinfectant.

(3) HIV/HBV claims. A claim for virucidal activity against HIV-1, HIV-2, or hepatitis B (HBV) viruses may be made only for use sites that involve human health care or other sites where there is a likelihood of soiling of inanimate surfaces or objects with blood or body fluids.

§ 156.449 Tuberculocidal claim on hard surfaces.

(a) Performance standard. (1) The product meets the performance standard of § 810.2100(d) as a broad spectrum disinfectant; and

(2) When tested in accordance with one of the test methods and standards in § 810.2100(h) of the guidelines or its equivalent, the product meets the performance standard for that test method in § 810.2100(h)(3).

(b) Acceptable claim. A product that meets the performance standard in paragraph (a) of this section may bear a claim of effectiveness as a "tuberculocide."

§ 156.451 Sanitizing claim on hard surfaces.

(a) Products for use on non-food contact surfaces--(1) Performance standard.
When tested in accordance with the test methods and standards in § 810.2100(l) of the guidelines or its equivalent, the product achieves at least a 99.9% (3-log) reduction in the number of test microorganisms over the parallel control count within 5 minutes.

(2) Acceptable claims. A product that meets the performance standard in paragraph (a)(1) of this section may bear a claim of effectiveness as a "sanitizer for hard, non-food contact surfaces."

(b) Products for use on previously cleaned food contact surfaces--(1) Performance standard for products containing halides. When tested in accordance with the test methods and test standards in § 810.2100(m)(1) of the guidelines or its equivalent, the product meets the performance standard of § 810.2100(m)(1).

(2) Performance standard for products not containing halides. When tested in accordance with the test methods and test standards in § 810.2100(m)(2) of the guidelines or its equivalent, the product achieves a 99.999 percent (5-log) reduction in the number of each test microorganism within 30 seconds.

(3) Acceptable claims. A product that meets the appropriate performance standard in paragraph (b) of this section may bear a claim of effectiveness as a "sanitizer for hard food contact surfaces."

(4) Unacceptable claims. A product labeled for food surface sanitizing may not bear a claim for "one-step" or combination cleaning and sanitizing. Sanitizing claims for food surfaces may be made only in conjunction with use directions that require a cleaning step prior to sanitization.

§ 156.452 Residual self-sanitizing claim on hard surfaces.

(a) Performance standard. When tested in a controlled or simulated in-use study under § 810.2100(o), whose protocol has been approved by the Agency, the product meets the performance standard of § 810.2100(o)(3).

(b) Acceptable claim. A product that meets the performance standard in paragraph (a) of this section may bear a claim of residual "self-sanitizing" activity keyed to the presence of moisture on surfaces that are likely to become and remain wet under normal conditions of use. A "residual" claim must also include the duration of effectiveness.

§ 156.453 Laundry additives.

(a) Pre-soak disinfection--(1) Performance standard. When tested in accordance with the test methods and standards in § 810.2300(b)(1) of the guidelines or its equivalent, the product meets the performance standard of § 810.2100(c),(d), and (e). Although the performance standard is the same for all disinfectant claims, the test standards and test microorganisms define the level of disinfectant claim that may be

made on product labeling.

(2) Acceptable claim. A product that meets the performance requirement in paragraph (a)(1) of this section may bear a claim as a "disinfectant" for pre-soaking fabrics prior to laundering.

(b) Pre-soak sanitization--(1) Performance standard. When tested in accordance with the test methods and standards in § 810.2300(b)(2) of the guidelines or its equivalent, the product achieves at least a 99.9% (3-log) reduction in the number of each test microorganism over the control count within 5 minutes.

(2) Acceptable claim. A product that meets the performance requirement in paragraph (b)(1) of this section may bear a claim as a "sanitizer" for pre-soaking fabrics prior to laundering.

(c) Non-residual disinfecting in-use additives--(1) Performance standard. When tested in accordance with the simulated-use procedure in § 810.2300(b)(3) of the guidelines or an actual in-use study whose protocol has been approved by the Agency, the product meets the performance standard of § 810.2300(b)(3).

(2) Acceptable claim. A product that meets the performance requirement in paragraph (c)(1) of this section may bear a claim as a "disinfectant" for use in laundry operations.

(d) Non-residual sanitizing in-use additives--(1) Performance standard. When tested in accordance with the test methods and standards in § 810.2300(b)(4) of the guidelines or its equivalent, the product meets the performance standard of § 810.2300(b)(4).

(2) Acceptable claim. A product that meets the performance requirement in paragraph (d)(1) of this section may bear a claim as a "sanitizer" for use in laundry operations.

(e) Residual self-sanitizing in-use additives--(1) Performance standard. When tested in accordance with the simulated-use procedure in § 810.2300(b)(5) of the guidelines or its equivalent, the product achieves at least 99.9% (3-log) reduction of each test microorganism over the zero-time and untreated control.

(2) Acceptable claim. A product that meets the performance standard in paragraph (e)(1) of this section may bear a claim of "residual self-sanitizer" for use in laundry operations when laundered articles are likely to become and remain wet (e.g., diapers), or be exposed to high humidity under normal conditions of use and storage.

§ 156.454 Fabrics and textiles.

(a) Carpets--(1) Performance standard. When tested in accordance with the test methods and standards in § 810.2300(c) of the guidelines or its equivalent, the product achieves at least a 99.9% (3-log) reduction in the number of test microorganisms over the scrubbed controls.

(2) Acceptable claims. A product that meets the performance standard in paragraph (a)(1) of this section may bear a claim as a "sanitizer" for carpets.

(b) Mattresses and upholstered furniture--(1) Performance standard. Only gas or fumigant treatments are acceptable for control of pathogenic microorganisms in or on these articles. When tested in accordance with a simulated use study under § 810.2300(d) of the guidelines, whose protocol has been approved by the Agency, the product meets one of the following standards:

(i) The performance standard in § 156.445(a) for a sterilizer.

(ii) The performance standard in § 156.446(a) for a disinfectant.

(iii) The performance standard in § 156.451(a) for a sanitizer.

(2) Acceptable claims. A product that meets the appropriate performance standard in paragraph (b)(1) of this section may bear the associated claim as a "sterilant," "disinfectant," or "sanitizer" for mattresses, upholstered furniture, pillows, and similar bulky articles. Separate directions for use must be provided for each claimed level of activity.

(c) Impregnated self-sanitiziing fabrics and textiles--(1) Performance standard. When tested in a controlled or simulated in-use study under § 810.2300(e)(3) of the guidelines, whose protocol has been approved by the Agency, the product meets the performance standard in § 156.452(a).

(2) Acceptable claims. A product that meets the performance standard in paragraph (c) of this section may bear a claim for "residual self-sanitizing" of treated fabrics and textiles in the presence of moisture. The duration of effectiveness must be specified.

§ 156.455 Air sanitizers.

(a) Performance standard--(1) Glycol-containing products. When tested in accordance with a protocol that has been approved by the Agency, the product achieves an actual glycol vapor concentration of at least 50% saturation in a test enclosure.

(2) Other products. When tested in accordance with a protocol that has been approved by the Agency, the product achieves, for each required test microorganism, at least a 99.9% (3-log) reduction in the number of viable microorganisms in the air of the test enclosure, after correction for settling rates.

(b) Acceptable claims. A product that meets either of the performance standards in paragraph (a) of this section may bear a claim as an "air sanitizer." This claim must be accompanied by a statement clearly indicating the mitigating level of the activity, such as "Temporarily reduces the number of airborne bacteria."

(c) Unacceptable claims. An air sanitizer may not bear a claim as a sterilant, disinfectant, or germicide.

§ 156.456 Toilets and urinals.

(a) Toilet bowls--(1) Performance standard. When tested in accordance with the test methods and standards in § 810.2100(c), (d), or (e), or § 810.2600(b)(2) of the guidelines or its equivalent, the product meets one of the following standards:

(i) The performance standard in § 156.446(a) for a disinfectant.

(ii) The performance standard in § 156.451(a) for a sanitizer.

(2) Acceptable claims. A product that meets the appropriate performance standard in paragraph (a)(1) of this section may bear the associated claim as a "disinfectant" or "sanitizer" for toilet bowl surfaces. Separate use directions must be provided for "disinfectant" and "sanitizer" levels of activity.

(3) Unacceptable claims. A product may not bear claims for disinfecting the hidden trap of the toilet, nor may a solution for tank use bear claims for disinfecting or sanitizing the bowl surface during flushing.

(b) Toilet bowl water--(1) Performance standard. When tested in accordance with a simulated-use study described in § 810.2600(c), the product achieves at least a 99.9% (3-log) reduction in the number of each test microorganism over the zero-time and parallel untreated inoculated controls.

(2) Acceptable claims. A product that meets the performance standard in paragraph (b) of this section may bear a claim as a "sanitizer" for toilet water.

(c) In-tank products--(1) Performance standard. When tested in accordance with a preliminary simulated in-use test and a laboratory efficacy test whose protocol has been approved by the Agency, the product achieves at least a 99.9% (3-log) reduction in the number of each test microorganism over the zero-time and parallel

untreated inoculated controls.

(2) Acceptable claims. A product that meets the performance standard in paragraph (c)(1) of this section may bear a claim as an "in-tank sanitizer" against pathogenic microorganisms in toilet water.

(3) Unacceptable claims. No claim other than sanitization may be made for toilet in-tank products.

§ 156.457 Human drinking water.

(a) Water treatment units and chemical substances--(1) Performance standard. When tested in accordance with the test methods and standards of the EPA Guide Standard and Protocol, the product achieves the reductions in the numbers of required test microorganisms (bacteria, viruses and protozoan cysts) given in the table below.

PERFORMANCE STANDARD REDUCTIONS FOR MICROBIOLOGICAL WATER PURIFIERS

Organisms	Minimum required reduction	
	Percent	Log
Bacteria	99.9999	6
Viruses	99.99	4
Protozoan cysts **or** Particles or spheres, 4-6 microns diameter (for filtration occlusion units)	99.9	3

(2) Acceptable claim. A product that meets the performance standard in paragraph (a)(1) of this section may be labeled as a "microbiological water purifier" or "microbiological water purification system."

(3) Unacceptable claim. A product that does not meet the performance standard in paragraph (a)(1) of this section for all test organisms required by the Guide Standard and Protocol may not bear on the labeling any terms or statements of express or implied "water purification" or variants thereof. Similarly terms such as "sanitize" or variants thereof, "pure" or "purify" and "hygienic" or variants thereof are not acceptable.

(b) [RESERVED]

§ 156.458 Swimming pool and spa water.

(a) Performance standard. (1) When tested in accordance with the test methods and standards in § 810.2700(d) of the guidelines or its equivalent, the product achieves efficacy equivalent to that achieved in a test using a sodium hypochlorite control; and

(2) When tested under in-use conditions (field test) under a protocol approved by the Agency, the product demonstrates that more than 85% of samples collected meet all of the following bacterial indices:

(i) The standard plate count at 35*C does not exceed 200 colonies per 1.0 milliliter (ml).

(ii) The most probable number of coliform bacteria is less than 2.2 organisms per 100.0 ml, or, if a membrane filter test is used, less than 1.0 coliform organism per 50 ml.

(iii) The most probable number of enterococcal organisms is less than 2.2 organisms per 100.0 ml, or if the membrane filter test is used, less than 1.0 enterococcal organism per 50 ml.

(b) Acceptable claims. A product that meets the performance standard in paragraph (a) of this section may bear a claim as a "disinfectant" for swimming pool water or water in hot tubs, jacuzzis, spas or whirlpools.